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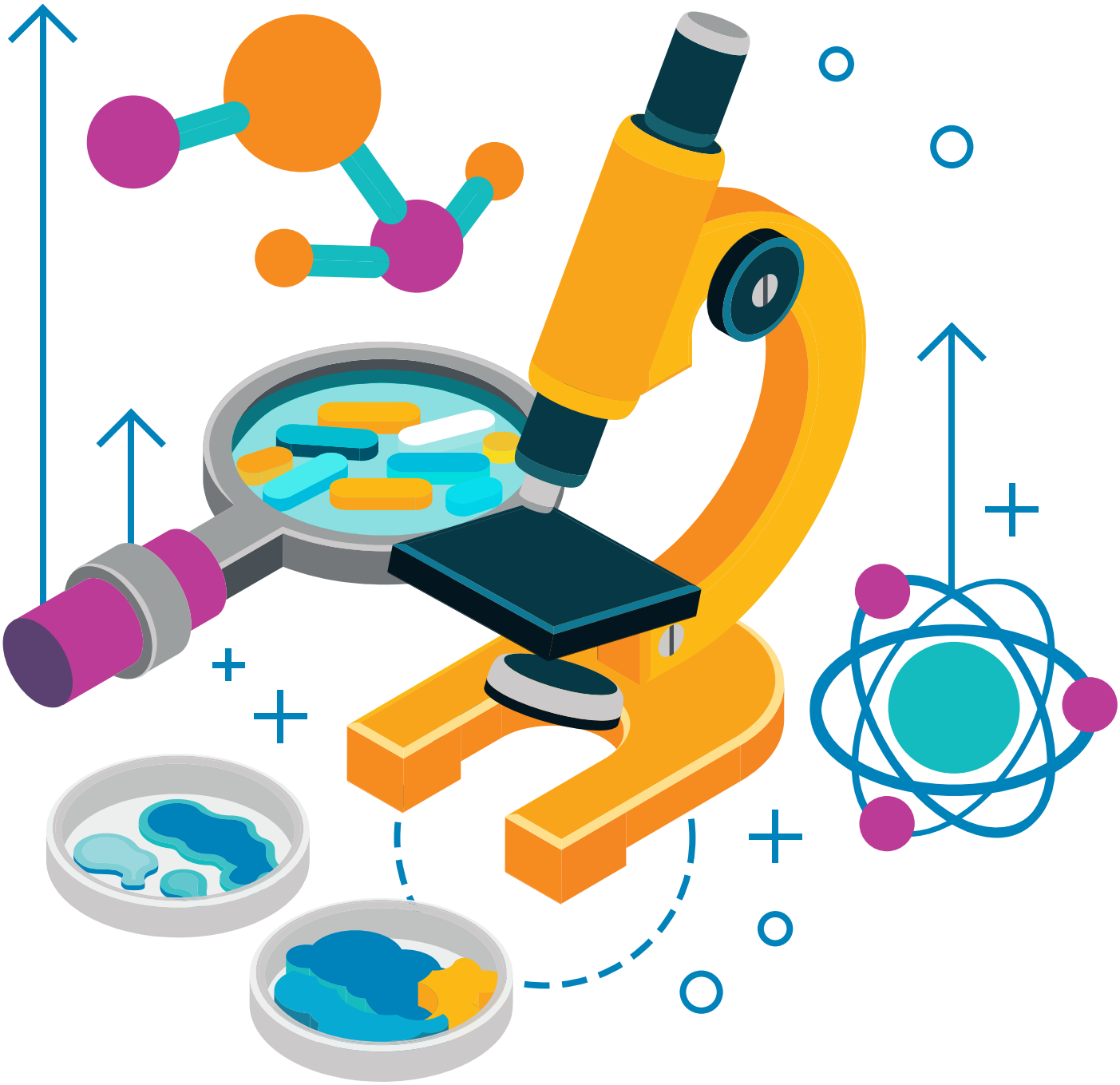
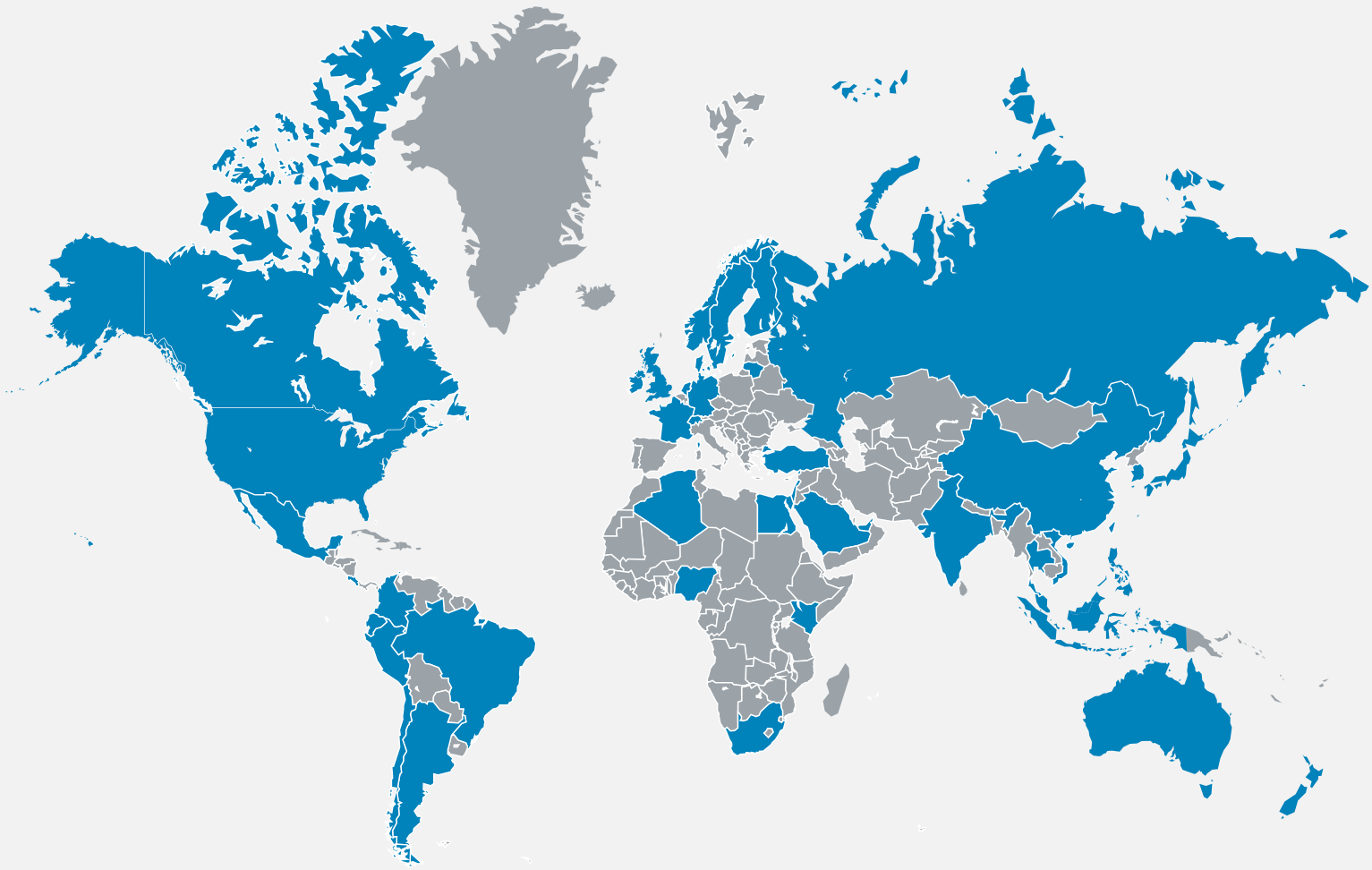


ANNEX
BUILDING THE BIOECONOMY 6TH EDITION
National Biotechnology Industry Development Strategies Globally

ANNEX – INDIVIDUAL COUNTRY OVERVIEWS AND STATISTICS

As detailed in the accompanying main report each country included in the Biotechnology Policy Performance Measure has been compared on each of the 30 indicators and categorized for each one according to the traffic-light classification system discussed above.

The data used as a basis for classifying and categorizing each country has been collected from international and national sources and databases. Below is a full individual country overview for each of the 44 countries included in *Building the Bioeconomy 2019* including all relevant statistics and information on which each country has been assessed.



ALGERIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	168 (World Bank 2005)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.1 (World Bank 2005)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Algeria does not provide RDP nor PTE; Achieved a score of 21.31% of total possible score for life sciences indicators in the International IP Index 2019	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	An independent regulatory agency (*Agence National des Produits Pharmaceutiques*) became operational in 2017, almost 10 years after its formal creation. However, the registration process remains slow and burdensome. Additional burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been implemented. For example, all registration dossiers must be pre-authorized prior to acceptance for review, but there is no transparent process or timeline for completing this preliminary step. Generics are not subject to bioequivalence requirement. Also, no regulatory framework is in place for biosimilars (a definition is contained in Health Law adopted in July 2018 at art 210). Algeria prohibits imports of almost all pharmaceutical products that compete with similar products manufactured domestically. 350+ products are listed as excluded from import, while annual import quotas are in place for products that are not locally manufactured. Recurrent delays in approving these quotas disrupt supplies to both patients and local manufacturers.	
Ag-biotech regulations	The Ministry of Agriculture's Decree of December 2000 prohibits all imports, production, distribution, and commercialization as well as utilization of genetically engineered plant materials, except for research purposes.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0 (score, 0-1)	The 2015 Research law foresees the creation of Innovation and Technology Transfer Centers. Yet, according to the Ministry of Research website, only one is being set up (in Sidi Abdellah), and incubators remain at the planning stage; The Algerian National Institute of Industrial Property (INAPI) supports the registration and commercialization of IP assets by academic researchers, research institutes and SMEs through its CATI network of support centers. These support centers – which as of 2018 numbered 48 in total – offers researchers and institutions technical support and expertise on the registration and commercialization of IP. In 2018 new support centers were announced in partnership with the Constantine's Center for Research in Biotechnology (CRBT).
Global Innovation Index 2018, University/Industry collaboration	2.6 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27	0.25 (score, 0-1)	Under art. 30 of the 2016 Finance Law the state has a Right of First Refusal on all transfers dealing with, or in favor of, foreign shareholders, where transfers are equal to or exceeding 10% of the foreign company's holdings in Algeria; furthermore, profits made from tax exemptions from corporate profits and professional activity must be re-invested in Algeria within 4 years. Any contract for goods and services imports is subject to domiciliation by an accredited intermediary. the State and Public Economic Enterprises (EPE) have a Right of First Refusal on all transfers dealing with foreign holdings. Any transfers beyond 10% of equity/ shares must be notified to the Council for State Participation (CPE).
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.25 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Pricing policies focus primarily on cost containment and there are strong preferences in place for local manufacturers. Since 2015, drug prices of innovative drugs (drugs with no generic competitor) are determined by international referencing, on the basis of the lowest prices from a list of five or six European countries. When a generic version exists, reference prices based on the cheaper generics, plus therapeutic reference prices for certain categories. Price negotiations must take place at the time of market authorization and must be done with two different bodies separately, the Price Committee of the Ministry of Health and the Reimbursement Committee under the Ministry of Labor. Article 23 of the Presidential Decree 10-236, 7th October 2010 establishes a 25% preference margin in all public contracts for Algerian products and companies completely owned by Algerians (100% Algerian capital). For those companies with less than 100% of Algerian capital, that 25% preference margin is prorated according to the percentage of Algerian capital in the country; 20% markup to pharmacists that replace an imported product with a local one.	
R&D tax incentives	Algeria does not provide any R&D or IP specific tax incentives. Some incentives, including exemptions from income and corporation tax, are available for industrial production but these are general and not aimed at high-tech or IP-intensive industries. More broadly Algerian tax law and administration is heavily geared towards localizing production and economic activity with mandates and requirements in place for local reinvestment.	
Factor 7: Rule of law	Ranked 72th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	57
Quality of academic publications, 2015	NA
Clinical trials per million population to date	2,28
Clinical trials for biologics per million population to date	0,07
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,00
Biotechnology triadic patenting, share of global total average 1999-2013	0,00%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	27,2
Biofuels production, % of global total, 2017	Negligible

ARGENTINA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	1,220 (2015)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.5% (OECD 2016)	
BERD spending as a % of total	18.2% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Neither RDP nor PTE available. Achieved a score of 32.31% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Important sanitary regulations are lacking: i) no bioequivalence requirement for generics; ii) poor pharmacovigilance. ANMAT regulation 6677/10 shortens delays for CT approval from 160 to 70 days; approvals are granted automatically if the delay is not respected.	
Ag-biotech regulations	Strong regulatory authority and science-based regulations for ag-bio: global leader with US, Brazil. 2015 saw introduction of "New Breeding Techniques" regulation for innovative biotech use in plants. Argentina was a global leader in introducing this. A record seven biotech approvals were issued in 2018. The seed royalty system continues to be an unresolved issue; a new Seed Law has been submitted to Congress.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score 0-1)	No overall framework in place for tech transfer from universities; CONICET (National Scientific and Technical Research Council) automatically owns 50% of any invention developed by public universities. Some high-profile examples of success stories in public-private tech transfer e.g. "National University of Litoral (UNL) and CONICET announced the successful completion of a nine-year research project supported by FONTAR, Argentina's Technology Fund. The project completed the discovery and isolation of a gene that makes plants resistant to drought and saline soil." CONICET has relatively well-developed tech transfer platforms in place.
Global Innovation Index 2018, University/Industry collaboration	3.3 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score 0-1)	Registering licensing agreements as well as tech transfer agreements with INPI is not required. While not affecting validity, failure to register has negative tax implications. Licensing conditions are generally described as favorable and flexible with a mere oversight role from government.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Caps on price growth introduced in recent years together with increased focus on cuts to reimbursement and preferential treatment for lower cost, locally manufactured medicines. Non-bioequivalence tested generic drugs (*similares*) a pervasive part of the market. In March 2018 the Minister of Health and provincial representatives agreed on a National Drug Strategy including mechanisms to reduce drug prices such as joint purchase and negotiations and capped prices for ambulatory drugs. In 2018 the Government submitted to the Senate a new proposal for the creation of the National Health Technology Assessment Agency (AGNET), which will assess products to be listed under the Compulsory Medical Program.
R&D tax incentives	General R&D tax incentive scheme in place is limited; for 2014/15 was capped at US$15million total budget. Additional incentives target software and biotechnology. Incentives for biotech range from VAT accelerated payments and a 50% tax credit on social security contributions.
Factor 7: Rule of law	Ranked 46th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	158,4
Quality of academic publications, 2015	NA
Clinical trials per million population to date	57,37
Clinical trials for biologics per million population to date	5,08
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1,29
Biotechnology triadic patenting, share of global total average 1999-2013	0,05%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	45,30%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	12,43%
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	56,2
Biofuels production, % of global total, 2017	3.7%

AUSTRALIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4,530 (2010 World Bank)	
Life sciences graduates (PhD & Masters), per million population	57.2 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.9 % (OECD 2015)	
BERD spending as a % of total	61.9% (OECD 2008)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	5.24 (OECD 2015)	
Biotech R&D as a percentage of BERD	1% (OECD 2015)	
Factor 3: Intellectual property protection	Both RDP and PTE are available. Since 2012, Australia's Department of Health has pursued market-sized damages (on top of those sought by the generic company) aimed at compensating the PBS for any higher price paid for a patented medicine during the period of a provisional preliminary injunction. Australia's market-size damages policy unfairly tips the scales in commercial patent disputes and creates an inappropriate conflict of interest by permitting the same government that examined and granted a patent to seek damages if that patent is later ruled invalid or not infringed. Achieved a score of 78.47% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Generally high standard of regulatory approval for biopharmaceuticals. A provisional approval pathway for NCE and new uses on the basis of early clinical data on safety and efficacy has been launched March 2018.	
Ag-biotech regulations	Regulatory hurdles in place for ag-bio cultivation: AUS federal government is generally supportive however significant restrictions have historically been in place at a state level e.g. the 2003 GM Free Areas Bill in Western Australia which was not repealed until Oct 2016. Australia's gene technology regulator proposed reducing regulations around gene editing techniques such as CRISPR, following a 12-month technical review into the current regulations.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Specific rules and guidelines of commercialization of IP assets from publicly-funded research are established in the "National Principles of Intellectual Property Management for Publicly Funded Research" of 2001; In addition, the Australian Government through IP Australia has launched the "Source IP" program - "a digital marketplace specifically created to help businesses and researchers collaborate by facilitating quick and easy contact", which provides businesses with access to public sector inventions and technology available for licensing and identifies collaboration opportunities, as well as promoting patent licensing and collaboration in public research institutions.
Global Innovation Index 2018, University/Industry collaboration	4.3 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score 0-1)	No registration process for licensing of IP rights. No significant barriers in place for private-private licensing and commercialization arrangements.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Number of product registrations relatively low and number of products included for reimbursement on PBS is low compared the high-income developed world averages. A 5-year agreement between the Department of Health and Medicines Australia was signed into law in 2018. It establishes price cuts that will deliver savings of USD1.8 billion at the condition that no further price reforms be undertaken up to 2023, and that savings be reinvested in drug purchase. Price cuts include a 5% statutory price reduction for drugs listed in the single-brand formulary for 5 years; a further 10% after 10 and 5% after 15 years; Post market reviews focused on cost containment.
R&D tax incentives	Tax offset for R&D spending is provided, based on revenues; 43.5% for revenues of less than AUD20 million, 38.5% for revenues over AUD 20 million and up to AUD 100 million, with 30% for revenues exceeding AUD100 million. the net benefit can range from 8.5% to 15% depending on the size of the taxpayer. Related overseas companies can fund an Australian-based R&D activity. Up to 50% of the total project costs of R&D activities can be physically performed outside Australia and remain eligible for benefits if the government has approved an advanced overseas finding
Factor 7: Rule of law	Ranked 11th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1668,8
Quality of academic publications, 2015	12,6
Clinical trials per million population to date	270,99
Clinical trials for biologics per million population to date	32,44
Early phase (Phase I and II) clinical trials for biologics, per million population to date	15,04
Biotechnology triadic patenting, share of global total average 1999-2013	1,66%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	27,30%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,47%
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	90,2
Biofuels production, % of global total, 2017	0.2%

BRAZIL

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	900.3 (2014 World Bank)	
Life sciences graduates (PhD & Masters), per million population	24.24 (OECD 2014)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.3 % (World Bank 2015)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	RDP and PTE for biopharmaceuticals unavailable; Long delays (10+ years) for patent applications reduce effective exclusivity period. A limited extension exists at part of the IP Law. RDP available for agricultural and veterinary products. Achieved a score of 44.22% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Dual examination requirement for biopharmaceutical patent applications outside international standards. ANVISA's Resolution No. 168/2017 clarifies the scope of ANVISA's 'prior consent' and limits it to public health considerations. Yet, ANVISA will still be able to issue a non-binding opinion on patentability requirements for products of interest to national drug prices. On a positive note unlike Argentina and other Latin American countries Brazil introduced bioequivalence testing requirements for all similares in 2003. Biosimilars pathway in place.	
Ag-biotech regulations	Ag-bio framework generally regarded as science-based and world-leading. The regulatory framework for agricultural biotechnology in Brazil is outlined in Law# 11,105 of March 25, 2005. two main governing bodies that regulate agricultural biotechnology in Brazil are the National Technical Commission of Biosafety (CTNBio) and the National Biosafety Council.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score 0-1)	PDP program governed under Ordinance 2531 2014 imposes obligation of technology transfer either through sharing/transferring the master drug file or cell bank from the international partner to the local Brazilian entity. While the PDP is a voluntary program between the MoH and private partners the successful PDP partner s provided exclusive supply status to the Brazilian public health care provider SUS for a maximum period of 10 years.
Global Innovation Index 2018, University/Industry collaboration	3.4 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score 0-1)	Tech Transfer contracts must be registered with INPI for it to have full effect in Brazil. Resolution No. 199/2017 of July 2017 adopted new rules of procedure for the registration of contracts that bring more flexibility to the registration process. In particular, the Resolution foresees that INPI shall no longer have a say on a license's duration, payments and contractual amounts. According to Normative Instruction No. 70/2017, INPI's analysis of tech transfer contract will be limited to the form of the contracts.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Generally challenging P&R environment. Prices regulated by the *Câmara de Regulação do Mercado de Medicamentos* (CMED) founded in 2003. Drugs are priced based on relative innovativeness compared to comparators – HTA process included in decision. IRP used extensively and calculated on lowest average ex-manufacturing price of the product in a basket of countries. Separate IRP calculation for "exceptional medicines" to which a "Coefficient Adequacy Price" or CAP is applied. Reimbursement decisions by CONITEC, SUS and MoH; largely based on cost analysis.
R&D tax incentives	R&D tax credits are in place under Law N. 11.196. These include a potential 160% super-deduction on eligible R&D related expenses. This deduction can also escalate rising to a maximum 180-280% when reaching certain conditions if there is a year-on-year cumulative increase in R&D spending and hiring practices. There is also an additional 20% deduction available once an invention has been patented. However, super deductions for patents are contingent on registration; long patent delays mean tax credit in effect is unavailable.
Factor 7: Rule of law	Ranked 58th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	185,3
Quality of academic publications, 2015	4,3
Clinical trials per million population to date	32,77
Clinical trials for biologics per million population to date	1,76
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,58
Biotechnology triadic patenting, share of global total average 1999-2013	0,12%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31,60%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	26,45%
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	57,4
Biofuels production, % of global total, 2017	22%

CANADA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4552 (World Bank 2014)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.6% (OECD 2018)	
BERD spending as a % of total	41.2% (OECD 2018)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	9.74 (OECD 2012)	
Biotech R&D as a percentage of BERD	2.7% (OECD 2012)	
Factor 3: Intellectual property protection	Canada offers RDP. Following negotiations of the Comprehensive Economic and Trade Agreement (CETA) with the EU, Canada introduced a two-year PTE. However, the term is made de facto unavailable by an export claw-out, restrictive time limits and eligibility criteria, and large Government discretion to share undisclosed test data without safeguards to protect against unfair commercial use. The U.S.-Mexico-Canada Agreement (USMCA) requires Canada to provide PTE and raise RDP to 10 years for biologics (up from 8 currently). Canada achieved a score of 65.78% in the International IP Index's life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Approximately 30% of drugs approved btw 1995 to 2016 benefitted from accelerated approval. A regulatory framework in place for subsequent entry biologics (SEBs): Health Canada's Biologics and Genetic Therapies Directorate (BGTD) regulates biosimilars in collaboration with the Regulatory Operations and Regions Branch (RORB) and the Marketed Health Products Directorate (MHPD). Yet, bureaucratic barriers exist in Canada that extend the time between submission to the federal government of newly discovered medicines and vaccines for safety approval, and their ultimate availability through public formularies to benefit Canadian patients. Canada is moving forward in implementing a national 'Pharmacare' reform whereby it will create a new national drug agency that would take a coordinated approach to assessing effectiveness and negotiating prescription drug prices on behalf of Canadians; a national formulary; and a national strategy for rare disease drugs.	
Ag-biotech regulations	Well established scientific approach since 1983, when the National Biotechnology Strategy (NBS) was created. A key element of the CBS was the establishment of the Canadian Biotechnology Advisory Committee (CBAC), an arms-length committee consisting of multidisciplinary experts and members of the general public.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score 0-1)	Canada does not have a national tech transfer framework in place. Universities have different policies with respect to technology transfer and ownership of IP. Registration of licensing deals is not a pre-requisite for licensing agreements and contracts to take legal effect Canada is home to the second largest life science cluster in North America – the Quebec-Ontario Life Sciences Corridor – with other significant clusters of activity in Vancouver, Alberta, and Atlantic Canada; Canada hosts various agricultural biotechnology clusters. More recently it launched the protein industrial 'supercluster' that uses plant genomics and novel processing technology to increase the value of key Canadian crops.
Global Innovation Index 2018, University/Industry collaboration	4.6 (score 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score 0-1)	Registration of licenses is no perquisite for licensing agreements and contracts to take legal, but can be an effective way of ensuring licensing contracts validity are easily upheld. No evidence that Canadian authorities interfere or set commercial terms of licensing agreements.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	The Patented Medicine Prices Review Board (PMPRB) regulates the maximum allowable price that a manufacturer can charge for a patented medicine to public or private payers. The Board has proposed draconian changes intended to set prices at levels paid by less wealthy countries. These changes would i.a. eliminate the US and Switzerland from the basket of countries used by the PMPRB to benchmark Canadian prices; oblige patentees to report all third-party rebates received in Canada; introduce the concept of 'affordability'/value for money into the PMPRB assessment; Investigate and start enforcement proceedings against patentees applying excessive prices.	
R&D tax incentives	Canada offers a volume-based R&D tax credit – the Scientific Research and Experimental Development tax credit. The tax credit is fully refundable at an enhanced rate of 35% of expenditure up to a limit of CAD3 million. In excess of this threshold, R&D expenses qualify for a credit at reduced rate of 15% that can be 40% refundable if some conditions are respected. The qualifying income limit starts at CAD500,000.	
Factor 7: Rule of law	Ranked 9th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	1 480,7
Quality of academic publications, 2015	11,5
Clinical trials per million population to date	541,76
Clinical trials for biologics per million population to date	39,94
Early phase (Phase I and II) clinical trials for biologics, per million population to date	18,28
Biotechnology triadic patenting, share of global total average 1999-2013	2,27%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	37,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	6,90%
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	92,6
Biofuels production, % of global total, 2017	1.5%

CHILE

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	502 (World Bank 2016)	
Life sciences graduates (PhD & Masters), per million population	18.2 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.4% (OECD 2016)	
BERD spending as a % of total	35.8% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	5-yr RDP term available. PTE calculations limit actual 5-year availability and heightened uncertainty through new recommendations by FNE committee in 2016. Government threatens use of CL for Hepatitis C treatment. Achieved a score of 45.25% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Generally high regulatory standards relating to biopharmaceuticals; Chile is achieved a Level 4 PAHO/WHO regional authority accreditation. However, *similares* are still on the market in Chile. "Ricarte Soto" Law introduced greater ambiguity and potential costs for companies around clinical trials. Amendments to the *Ley de Farmacos II* would significantly limit the use of trademarks in biopharmaceutical product.	
Ag-biotech regulations	Chile does not allow for the cultivation of ag-bio products. Only production of seeds is allowed for export purposes. No biotechnology framework in place. The Ministry of Health (MOH) requires the producer or importer that produce products that contain GE ingredients to register the products.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score 0-1)	CORFO has in place a number of tech transfer initiatives including Technology Transfer Hubs and Start-Up Chile. Some examples of success stories e.g. *Fundación Chile*, a well-established not-for-profit NGO, has had several successful biotech collaborations in the past including R&D collaborations in fruit and forestry biotechnology with US and Canadian biotech firms. A new tech transfer law covering all public funds is reportedly being prepared.
Global Innovation Index 2018, University/Industry collaboration	3.5 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 .75 (score 0-1)	Registration not compulsory but makes the act opposable. The law does not interfere in international licensing terms. Yet, the Government has been used the threat of compulsory licensing for expensive drugs as a way to contain prices.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.75 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	No central price control with public sector prices negotiated via public tenders through *Central Nacional de Abastecimiento* (CENABAST) or directly with public institutions. Minimum 30% discount for CENABAST-negotiated medicines. Reimbursement policies vary but long-standing insecurity of reimbursement for high-cost treatments resulted in "Ricarte Soto" Law (Law 20,850) which aims to increase the level and scope of funding for high-cost treatments with an initial budget of around USD35 million in 2015 that increased to nearly USD200 million in 2018, providing full reimbursement to expensive drugs treating 18 health conditions (4 more than in 2017).
R&D tax incentives	Volume based R&D tax credit introduced in 2008 (Law No. 20.241) modified in 2012 to include also intra-mural R&D expenses (Law No. 20.570): tax credit of 35% of payments associated with R&D pre-certified expenditure, which covers certified contracts entered into with a registered research center and R&D activities carried out in-house, with an annual cap of UTM15,000 (approximately US$1.2 million).
Factor 7: Rule of law	Ranked 25th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	241,5
Quality of academic publications, 2015	5,8
Clinical trials per million population to date	80,20
Clinical trials for biologics per million population to date	8,14
Early phase (Phase I and II) clinical trials for biologics, per million population to date	2,82
Biotechnology triadic patenting, share of global total average 1999-2013	0,03%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28,80%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,01%
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	68,1
Biofuels production, % of global total, 2017	Negligible

CHINA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	1,205.7 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2.1 % (OECD 2017)	
BERD spending as a % of total	76.5% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	6-yr RDP term available but limited protection for biopharmaceuticals; only applies to NCEs. Ongoing reform extends protection to biologics but with provisions that disproportionally favor local drugs. No PTE available; 2019 draft amendments to the Patent Law propose introducing it, but with important flaws. New linkage mechanism introduced; has potential to greatly improve existing exclusivity enforcement mechanisms in China for innovators. Achieved a score of 45.31% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Draft Opinion N.42 (or "Innovation Opinion") kick-started a large, groundbreaking revision of drug laws by the the National Medical Products Administration (NMPA). In particular, it adds a conditional approval pathway for drugs and medical devices that fulfill unmet medical needs and simplify the CT approval process. More recently the NMPA established a "special channel" for the review and approval of new drugs approved and marketed in the US, EU, or Japan in the past 10 years, but not yet approved in China.These measures are aimed at tackling substantial delays in product and clinical trial registration. Regulatory gaps exist with regard to pharmacovigilance policies and enforcement. Positively, the 2015 biosimilar pathway broadly reflects the approach taken in the EU and US.	
Ag-biotech regulations	A number of regulatory related barriers to market entry persists. They include: the requirement that a product must be registered and approved in the country of export prior to an application for approval can be made in China; and a requirement that import applications include viable seeds. In 2018, the Chinese Ministry of Agriculture and Rural Affairs amended the regulations on safety assessment, import approval, and labeling of agricultural GMOs without notifying the changes to the WTO nor soliciting comments from stakeholders. The revised rules impose additional in-country trials and studies on new biotech events as part of the dossier submission process.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score 0-1)	Tech transfer framework in place encouraging high levels of commercialization. Relative freedom for universities and researchers to pursue commercial ventures has seen a sharp increase in university patenting, patent and technology transfers and number of spin-offs where Chinese academics are world-leaders.
Global Innovation Index 2018, University/Industry collaboration	4.4 (score 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score 0-1)	More serious barriers are in place for private-to-private licensing and commercialization activity. Technology import/export regulations involve discriminatory conditions for foreign licensors, including indemnification of Chinese licensees against third-party infringement and transfer of ownership of future improvements on a licensed technology to the licensee.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Cost containment measures designed to make medicines more accessible for patients have largely hindered innovative drugs from entering the Chinese market. Prices are increasingly contained by reimbursement and tendering procedures, as well as price limits on certain types of drugs. The public Essential Drug List restricts the number of "high-cost" drugs that can be prescribed in local hospitals and clinics. A strict and limited reimbursement procedure also exists, in spite of recent improvement. The National Reimbursed Drug List was updated in 2017 for the first time in 8 years. 36 oncologic drugs were added in 2017 and 17 in 2018. The National Healthcare Security Administration is in the process of establishing a negotiation process and a regular reimbursement mechanism.	
R&D tax incentives	Generous R&D tax credits and target high-tech industries (including biotech) but local ownership requirements/partnerships in place.	
Factor 7: Rule of law	Ranked 82nd out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	201,8
Quality of academic publications, 2015	7,6
Clinical trials per million population to date	10,08
Clinical trials for biologics per million population to date	0,83
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,54
Biotechnology triadic patenting, share of global total average 1999-2013	1,03%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	15%
Biotechnology crops, hectares under cultivation, % of total 2016	1,48%
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	80,7
Biofuels production, % of global total, 2017	2.6%

COLOMBIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	132 (2015 World Bank)	
Life sciences graduates (PhD & Masters), per million population	6.44 (2016OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.3% (2016 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	5-yr RDP term available but uncertainty over protection for biologics. No PTE available. CLs threats used as a means of price negotiation. Achieved a score of 44.28% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	2016 reforms to biopharma CTs environment improved CT approvals. Biologic market approval dedicated pathways in place since 2014 (Decree 1782), included an abbreviated route for the registration of non-comparable products that is regarded as substandard - inconsistent with WHO standards and practices in other countries.	
Ag-biotech regulations	Ag-bio regulations science-based but time consuming. Uncertainties due to labeling and approval issues, and ongoing discussions around key biotechnology regulations, e.g. on GE labeling.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score 0-1)	Colombian public sector researchers and university faculty are not allowed a second salaried income that essentially means that the incentives to set up new businesses through spin-offs or start-ups are limited. Colombian law prohibits any non-profit organization, including private universities, from engaging in commercial activities.
Global Innovation Index 2018, University/Industry collaboration	3.6 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score 0-1)	ANDEAN decision 291 adds significant restrictions on agreements with foreign licensors, requiring registration and evaluation of licenses by national authorities on the basis of subjective criteria regarding the so-called value of imported technologies.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Maximum sales prices for all medicines are since the signing into law of the 2015 health reform package (*Ley Estatutaria de Salud*, 1751) vested within the Ministry of Health. Drug prices set by the Ministry of Health are applicable to both private and public markets based on a system of international reference pricing. Prices are set according to wholesale levels with margins monitored by the Ministry of Health. A list of 148 drugs to be subject to direct price control has been issued in 2018. Significant price cuts and reimbursement limits have been introduced and the Colombian Government has introduced more extreme price control measures including the threat of using compulsory licensing. The MoH adopted a resolution with criteria for the centralized purchase, distribution and supply of medicines for the treatment of prioritized diseases.
R&D tax incentives	A tax discount of 25% is available for investments in science, technology and innovation projects. The discount can be taken any year after qualification through a process before the Administrative Department of Science, Technology and Innovation (COLCIENCIAS). The budget available is subject to a yearly cap.
Factor 7: Rule of law	Ranked 80th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	62,8
Quality of academic publications, 2015	NA
Clinical trials per million population to date	24,86
Clinical trials for biologics per million population to date	2,93
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,88
Biotechnology triadic patenting, share of global total average 1999-2013	0,01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,05%
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	63,3
Biofuels production, % of global total, 2017	0.7%

COSTA RICA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	573 (2014 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.6% (2014 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD		
Factor 3: Intellectual property protection	5-year RDP, including for biologics but excluding new uses or indications, changes in the route of administration, dosage, dosage forms and formulation, and new combination drugs. 18-month PTE for delays of at least 3 years from filing marketing approval and 5 years from filing a patent. Achieved a score of 50.69% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The Department of Regulation of Products of Sanitary Interest (DRPIS) within the Ministry of Health commits to approve innovative drugs and biologics within 99 days. Since 2016 accelerated procedure in place with the DRPIS recognizing approval reports issued by stringent regulatory authorities. In 2010 the Constitutional Court suspended all clinical investigations on humans until new laws were enacted; "Law for the Regulation of Biomedical Research" (Law 9234) was passed in 2014.	
Ag-biotech regulations	Ag-bio transgenic seed varieties have been grown in Costa Rica since 1992 with all seeds being exported to other countries. Legal proceedings halted the National Technical Biosafety Commission ability to approve further products. The Commission resumed regular meetings in 2016 and in 2017 and approved a cotton event for seed reproduction in June 2017; large number of municipalities or local governments declared themselves 'free from transgenic'.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score 0-1)	A legislative framework ruling commercialization of public research outcomes is in place (Law 7169 art 94). Yet, the link between industry and research is still weak – except for ag-bio – and hasn't significantly improved as reported by the OECD STI Review of 2017. OECD also talks of a preliminary, experimental stage for technology transfer offices. Costa Rica has six Technology and Innovation Support Centers active in main universities to support patenting activities.
Global Innovation Index 2018, University/Industry collaboration	3.6 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score 0-1)	Patent and design licenses – but not trademark ones – have to be registered at the National Registry. Generally speaking, licensing terms are not controlled.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	No price regulation is in place now, though a bill proposes introducing price caps and maximum profits for distributors and pharmacies, and creating an authority for Drug Price Control within the Ministry of Economy. Costa Rica's Social Security Fund (*Caja Costarricense de Seguro Social*) since 2009 regulates the purchase and negotiates prices of biotech and biologic drugs. Any biotech and biological product commercialized in Costa Rica has to be registered and commercialized in at least one Stringent Regulatory Authority.
R&D tax incentives	No direct R&D tax incentives. Scientific research firms can benefit from the Free Trade Zone System regime which provides i.a. full exemption from custom duties, withholding tax on royalties and fees, interest income, sales tax on local purchases of goods/services.
Factor 7: Rule of law	Ranked 24th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	55,6
Quality of academic publications, 2015	NA
Clinical trials per million population to date	34,45
Clinical trials for biologics per million population to date	3,47
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,61
Biotechnology triadic patenting, share of global total average 1999-2013	0,00%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,01%
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	NA
Biofuels production, % of global total, 2017	Negligible

DENMARK

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	7,515 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	229 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3.1 % (OECD 2017)	
BERD spending as a % of total	58.3% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	192.7 (OECD 2013)	
Biotech R&D as a percentage of BERD	22.5% (OECD 2013)	
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Not included in IP Index.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High regulatory standards for biopharmaceuticals (both EMA and national agency, *Laegemiddelstyrelsen*).	
Ag-biotech regulations	Denmark has banned GMO cultivation and is one of 19 EU Member States to have opted out from Commission approved cultivation of a GM crop.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	NA	Denmark was one of the first EU countries to put in place technology transfer legislation supporting university commercialization of publicly funded research. Denmark also provides a number of funding measures to help young and innovative biotechnology companies thrive. Reportedly four out of five companies in the life science sector collaborated with a Danish university between 2014 and 2016; more than half of all Danish life science companies are located less than five kilometers from a university. Cooperation also benefits from the Medicon Valley Biotech Cluster, a Danish-Swedish cross-border initiative.
Global Innovation Index 2018, University/Industry collaboration	4.8 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	NA	IP licenses are in general not registered. License registration is possible but is of a formal nature and does not affect the validity of the license
Direct Government intervention in setting licensing terms (IP Index indicator 28)	NA	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	By European standards the pricing and reimbursement environment for biopharmaceuticals is less stringent than other countries. Price controls are only indirectly in place with agreements between the Danish pharmaceutical industry and MoH. Reference pricing system in place and heavy use of generic substitution and promotion policies.	
R&D tax incentives	Tax credits and deductions are available as R&D incentives. The R&D tax credit is up to 25% with a maximum cap of 25 million Danish Crowns.	
Factor 7: Rule of law	Ranked 1st out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	1861,6
Quality of academic publications, 2015	14,2
Clinical trials per million population to date	1278,77
Clinical trials for biologics per million population to date	66,04
Early phase (Phase I and II) clinical trials for biologics, per million population to date	25,83
Biotechnology triadic patenting, share of global total average 1999-2013	1,70%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	44,90%
National % share total number of patents from top 50 PCT applicants: universities, 2016	1%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	84,3
Biofuels production, % of global total, 2017	Negligible

ECUADOR

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	400.7 (2014 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.4% (2014 World Bank)	
BERD spending as a % of total		
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Ecuador provides 5-year RDP, but no PTE; achieved a score of 25.91% in the International IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The authority responsible for applying and enforcing the regulatory framework in relation to human medicines, biologicals, and medical devices is the National Agency for Regulation, Control and Sanitary Surveillance (ARCSA), a decentralized agency of the Health Ministry. A reliance pathway (referred to as 'Homologation procedure') is applicable to new registrations previously approved by drug authorities in the EU, US, Australia, Canada, Japan, South Korea and PAHO Regional Level IV authorities – which ensure speedy approvals. Homologation efforts ongoing also for drugs approved in Mexico. Concerns over quality and pharmacovigilance standards. Regulations for biosimilars in place (ministerial agreement 3344), currently being revised.	
Ag-biotech regulations	At article 401 of the Constitution Ecuador is declared free of transgenic crops and seeds. On June 1, 2017, Ecuador's National Assembly approved the "Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture" that side-steps the constitutional ban on the cultivation of GE crops by permitting GE crop cultivation for research purposes. The Ministry of Agriculture and Livestock is drafting specific guidelines for the implementation of this law. The law has been challenged at the highest court by anti-GMO groups, and the issue is awaiting decision.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score 0-1)	Technology transfer and the creation, dissemination, commercialization and eventual export of knowledge created products and services was/is an elemental part of the *Código Ingenios*. Article 276 of the IP chapter provides a clear distribution of right and royalties related to any innovations made at universities, higher education institutes and public research organizations. These entities keep ownership, and the researchers should be assigned no less than 40% of royalties. High profile initiative to foster public private collaboration is the 'City of Knowledge Yachay' in rural Ecuador.
Global Innovation Index 2018, University/Industry collaboration	3 (score 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score 0-1)	Article 12 of Andean Decision 291 states that all licensing activity should be recorded and evaluated by the respective national authorities. Hence, failure to register trademarks and patents may result in licensing agreements being declared void. Article 276 of the *Código Ingenios* (IP chapter) provides that at least 40% of royalties related to any innovations made at universities, higher education institutes and public research organizations be assigned to inventor.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Prices of essential and new drugs are capped by the Ministry of Health through the National Council for Fixing and Reviewing Drug Prices (CNDP), as per Prices Decree 400/2014. The price caps for each segment will be calculated with the average of the retail prices in the private market. For new medicines, the level of therapeutic innovation will be used as the basis for establishing the price cap. If companies do not respect price caps the Government unilaterally sets prices only in specific situations. For all other products manufacturers are free to set prices but have to notify the CNDP. The EDL is updated every second year.
R&D tax incentives	No general R&D or IP specific tax deductions, credits or incentives in place. Science and technology-based incentives are available for investment in special economic zones (*Zonas Especiales de Desarrollo Económico*) as are other tax and investment incentives. Some expense deductions apply for R&D trainings and assets for the purposes of calculating income tax.
Factor 7: Rule of law	Ranked 87th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	17,3
Quality of academic publications, 2015	NA
Clinical trials per million population to date	7,34
Clinical trials for biologics per million population to date	0,18
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,06
Biotechnology triadic patenting, share of global total average 1999-2013	0,00%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	22,10%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	45,2
Biofuels production, % of global total, 2017	Negligible

EGYPT

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	680.3 (World Bank 2016)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.7 (World Bank 2016	
BERD spending as a % of total		
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Both RDP and PTE unavailable. Achieved a score of 27.47% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The Egyptian Drug Authority is the pharmaceutical regulatory body of the MoH, but Egypt is in the process of establishing a new medicines authority independent from the MoH. In 2017 Egypt introduced a 30-day verification procedure for approval of new chemical entities and biologics already approved by EMA and FDA, and a 60-day abridged procedure if the new product is approved by only one of them. Guidelines on registration of biological products in place (decree 150/2015) and in line with WHO standards. Egypt regulated clinical activities in 2016 through the National Guidelines and Regulations for Good Clinical Practice (Decree no. 734/2016) Before that, facilities for clinical research could not be accredited by foreign regulators. Large availability of counterfeit drugs as an effect of insufficient control and unclear supply chain, though a track and trace system is in place since 2016.	
Ag-biotech regulations	Egypt lacks a biosafety framework that defines a transparent and clear policy for biotechnology, although biotech products have already been commercialized. the government permits biotech imports so long as country-of-origin also consumes these products. Egypt does not require labeling of biotech products. Ministerial Decree 378/2012 suspends the registration, cultivation, and commercialization of all genetically engineered crops. A Biosafety Bill has been proposed, which should facilitate field trials and commercial use of GMOs. Creation of a National Food Safety Authority (NFSA) was approved by Parliament in December 2017 and is expected to bring more clarity to GMO rules and adopt science-based rules facilitating GE trade.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	Egyptian law grants ownership of IP to the employer (and as such also universities) but lacks clarity and further details. A few Egyptian universities, such as Alexandria University and American University in Cairo, have technology transfer offices in place. The Academy of Scientific Research and Technology (ASRT), and in particular the Invention & Innovation Development Agency, fosters technology transfer in the country and coordinates the National Network of Technology and Innovation Commercialization Offices in the country's main public research organizations. ASRT also provides grants for the creation of Regional Technological Incubators and innovation clusters known as the Knowledge and Technological Alliances. Yet, a lack of nonfinancial and business support remains a major barrier for innovators willing to commercialize their inventions.
Global Innovation Index 2018, University/Industry collaboration	2.8 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	All licensing deals/contracts pertaining to all major forms of IP rights need to be registered with the relevant authorities. No formal barriers in place for licensing deals between private-private entities or foreign and local Egyptian entities apart for "process secrets". A stiff withholding tax is levied on royalty payments unless a double taxation treaty exists. The U.S.-Egyptian treaty for the avoidance of double taxation limits the tax on royalty payments to 15% of the gross amount of such royalty.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	External reference pricing was introduced in 2009 and mark-up regulation was added in 2012. Strict price controls in place and ad hoc price cuts taking place since 2011. The government has yet to implement the price increases pledged after the drastic currency devaluation experienced in 2016. Wide-spread shortages reported including for basic medicines such as insulin, vaccines and contraceptives.	
R&D tax incentives	No R&D tax incentives in place. The new Investment Law 2017 foresees a 30% deduction of investment costs from taxable net profit for certain industries, including manufacturing of antibiotics and oncology products, and agricultural crops and recycling of agricultural waste.	
Factor 7: Rule of law	Ranked 121st out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	68,3
Quality of academic publications, 2015	NA
Clinical trials per million population to date	31,20
Clinical trials for biologics per million population to date	0,75
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,35
Biotechnology triadic patenting, share of global total average 1999-2013	0,00%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	10,30%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	52,7
Biofuels production, % of global total, 2017	Negligible

FINLAND

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	6,525 (OECD 2016)	
Life sciences graduates (PhD & Masters), per million population	89.8 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2.8% (OECD 2017)	
BERD spending as a % of total	57 (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	15.2 (OECD 2015)	
Biotech R&D as a percentage of BERD	1.6 (OECD 2015)	
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Substandard IP protection for pharmaceutical patents filed before 1995 fully phased out in 2019. Not included in the International IP Index.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High regulatory standards for biopharmaceuticals by the Finnish Medicines Agency (FIMEA) and EMA.	
Ag-biotech regulations	Finland is among the EU countries with a pragmatic, open approach to ag-bio technology; the country allows field trials and cultivation of GMOs, though this does not take place.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	Not included	Since 2007, the Act on the Right in Inventions made at Higher Education Institutions grants property of publicly funded inventions to universities. Intensifying cooperation between higher education and business to commercialise innovations is a key priority of the Health Growth Strategy. To support this goal, competence hubs and innovation campus operating models around university hospitals have been supported. The Health Capital Helsinki, a leading life sciences hub, is one such example. Business Finland runs thematic networks, including one on the bioeconomy and one on health and wellbeing, to connect domestic and international research organizations, companies, and other interest groups. Other initiatives include the SPARK Finland development program, which aids researchers and clinical health care professionals to create new products and business solution for the unmet needs of health care.
Global Innovation Index 2018, University/Industry collaboration	5.6 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	Not included	IP licenses can be recorded with the relevant registers maintained by the Finnish Patent and Registration Office. Registration makes them enforceable against third parties.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	Not included	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Because of the lower protection granted by analogy process patents, originators have in some cases been subject to reference pricing (in place since 2009) and generic substitution, resulting in rapid price erosion both in Finland and other EU members that reference its prices. Positively, the last analogy process patents expired in 2019. In 2017 the Government agreed with local stakeholders, including industry, on cost-containment measures that increased competition for biologics and biosimilars. As concerns reimbursement, innovative solutions such as adaptive reimbursement are being implemented in parallel to more punitive measures, notably the inclusion of imported generic medicines in the reference price system. On a positive note, Finland has set the target of 5% of all public procurement being innovative in nature.	
R&D tax incentives	Finland offers accelerated depreciation for R&D expenses, including expenditure incurred abroad.	
Factor 7: Rule of law	Ranked 3rd out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	1788,6
Quality of academic publications, 2015	11,4
Clinical trials per million population to date	526,92
Clinical trials for biologics per million population to date	45,72
Early phase (Phase I and II) clinical trials for biologics, per million population to date	15,60
Biotechnology triadic patenting, share of global total average 1999-2013	0,44%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	43,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	82,2
Biofuels production, % of global total, 2017	0.3%

FRANCE

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4307 (2015 World Bank)	
Life sciences graduates (PhD & Masters), per million population	140,3 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2.2% (2017 OECD)	
BERD spending as a % of total	54% (2015 OECD)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	53,2 (2016 OECD)	
Biotech R&D as a percentage of BERD	8.95% (2016 OECD)	
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Not included in the International IP Index.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High regulatory standards for biopharmaceuticals by the National Agency for the Safety of Medicines and Health Products and EMA. France offers early access to promising therapies in areas of high unmet need through the Temporary Authorization of Use (ATU) pathway. The Social Security Finance Bill 2019 proposed to extend this system also to new indications.	
Ag-biotech regulations	France authorizes imports of GE products but restricts research and bans cultivation of GE crops for environmental concerns. France is one of 19 EU MS to opt out from Commission approved cultivation of a GM crop. It has no commercial production or field trials of genetically engineered (GE) crops. Some fundamental research is being conducted in labs.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	The 1999 Innovation Law enabled education facilities and state funded research centers to create spin-offs. As of 2013, over 50% of biotech firms founded in France were spin-offs from academic research. Yet, fragmentation of public institutions limited private investment in R&D in universities are regarded as existing barriers to further tech transfer. Other initiatives include the Health Biotechnology Innovation Network (RIBS) was created in 2004 to support innovative R&D projects collaborations between research organizations and companies.
Global Innovation Index 2018, University/Industry collaboration	4.2 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	French IP law does require the registration of licensing agreements to be held effective against third parties. Licensing agreements are not subject to Government review or scrutiny unless it is in specific sectors relating to national security.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Capped drug spending with threshold triggering safeguard clause and repayment from industry has been in past years set at 0%. For each of the next three years, overall pharmaceutical expenditure will be permitted to grow by a minimum of 0.5% (equivalent to 1% of reimbursed expenditure). It was announced, but not implemented, that spending on innovative drugs will be permitted to increase by at least 3% per year. The industry (national biopharma association LEEM) still considers that pharma is unduly targeted by spending cuts and bears the weight of most savings
R&D tax incentives	The French State introduced the Research Tax Credit (CIR) in 1983. Since 1 January 2008, the CIR is based on R&D volume only: 30% of R&D expenditure for up to 100 million euros, then 5% of R&D expenditure beyond this threshold. For companies that ask benefit for the first time, the rate of the first installment is 50% the year of entry into the scheme and 40% the second year. Since 2013 the CIR is supplemented by an innovation tax credit, covering a range of innovation and design expenses other than R&D, up to 400,000USD. SMEs can benefit from an immediate refund of unused tax credits in the case of loss. Large businesses can carry forward such credits up to 3 years.
Factor 7: Rule of law	Ranked 17th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1 002,3
Quality of academic publications, 2015	10,3
Clinical trials per million population to date	326,03
Clinical trials for biologics per million population to date	28,74
Early phase (Phase I and II) clinical trials for biologics, per million population to date	7,51
Biotechnology triadic patenting, share of global total average 1999-2013	5,16%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	37,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	79
Biofuels production, % of global total, 2017	2.6%

GERMANY

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4893.2 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	119.2 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3% (2017 OECD)	
BERD spending as a % of total	65.2% (2016 OECD)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	17.33 (2017 OECD)	
Biotech R&D as a percentage of BERD	1.8% (2017 OECD)	
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Achieved a score of 92.53% on the International IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High biopharma regulatory standards upheld by the Federal Institute for Drugs and Medical Devices (BfArM) and EMA, including EMA's biosimilar pathway.	
Ag-biotech regulations	A draft legislation from November 2016 banning the cultivation of GE crops remains pending because of disagreement regarding whether the ban might cover the entire country, or be decided individually by each of the German states. Germany has opted out from GE cultivation under the EU Directive. It also has legislations and/or guidelines in place to facilitate GE-free labelling.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Germany has a sophisticated system of commercializing public and university research. A number of Government programs and policies are in place to incentivize innovation and technology transfer including: the 2002 University IP Ownership Law, Successive High-tech Strategies, TTOs (regionally and university based), PROs (Fraunhofer institutes). Germany is one of the highest performers on key indicators including industry sponsorship of higher education R&D.
Global Innovation Index 2018, University/Industry collaboration	5.4 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score, 0-1)	German law does not require the registration of licensing agreements. Contracts for the licensing of patents, trademarks and other forms of IP rights can be executed freely and are governed by relevant contract law.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	A very regulated, cost driven pricing system in place since 2011 (AMNOG legislation) modified by the German Act on Strengthening Pharmaceutical Supply in the Statutory Health Insurance (GKV-SV) in force since May 2017. The AMNOG system foresees 7% mandatory rebate for innovative patented products (i.e. drugs not covered by fixed reference prices) and a price moratorium recently extended until 2022. Strict rules are in place for HTA assessment. For instance, the Federal Joint Committee (G-BA) assesses cancer drugs based on survival rates and not on overall response rate.
R&D tax incentives	German tax law does not offer any R&D based or IP-specific incentives. Instead, German R&D incentives are focused on non-repayable R&D grants. These grants normally make up 50% of a given project with higher levels available for SMEs. In 2017, the federal government spent €17.1 billion, with €7.4 billion going directly to specific projects. Also, introduction of R&D tax incentives has been proposed in 2019 by the Finance. Proponents of tax breaks say action is needed to achieve the government's target of raising national R&D spending to 3.5% of GDP.
Factor 7: Rule of law	Ranked 6th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1 139,4
Quality of academic publications, 2015	12,1
Clinical trials per million population to date	219,88
Clinical trials for biologics per million population to date	16,25
Early phase (Phase I and II) clinical trials for biologics, per million population to date	7,56
Biotechnology triadic patenting, share of global total average 1999-2013	8,55%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	55%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	87,7
Biofuels production, % of global total, 2017	3.9%

INDIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	216 (2015 World Bank)	
Life sciences graduates (PhD & Masters), per million population	40.6 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.6 % (2015 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	No RDP term or PTE available. Generally, a challenging IP environment with heightened patentability standards (section 3D) and use of CLs. Achieved a score of 27.59% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Under-developed biopharmaceutical regulatory framework; high levels of substandard and counterfeit medicines. Draft New Drugs and Clinical Trials Rules have been published but still await adoption. They introduces specific timelines to CT approval; 45 days for drugs developed in India (including a proposal to manufacture in India) and 90 days for new drugs already marketed in a list of countries defined by the CDSCO; they introduce conditional marketing approval for orphan drugs; they also expand definition of drugs to include stem-cells and cell-based products, bringing CTs on these products under CDSCO regulation. In May 2018 India announced plans to create a single-window system for new drug approval to boost ease of business and contribute to the Make in India Initiative. Biosimilars pathway in place.	
Ag-biotech regulations	No ag-bio applications approved since 2011. India's political landscape continues to hinder the agricultural biotech regulatory system, creating uncertainty throughout the agricultural biotechnology sector. Recently, the Government deferred the approval for a locally-developed genetically engineered (GE) mustard event which had been cleared by the regulatory authorities in May, 2017.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	Technology transfer and commercialization of public funded research remains relatively limited. Identified as a key priority in the National Biotechnology Development Strategy and National Intellectual Property Rights Policy. Yet very few Indian universities have functioning TTOs and outputs relatively sparse.
Global Innovation Index 2018, University/Industry collaboration	4.4 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score, 0-1)	Registration of patent licenses is mandatory under the Patent Act. Articles 68 and 69 outline the basis and requirements of registration. Case law suggests that licenses not registered in the prescribed manner have been held as invalid (e.g. New Delhi High Court ruling in the 2009 *National Research Development ... vs M/S Abs Plastics Limited* case). There is also an administrative requirement ('Form 27') that patent holders yearly provide information about the manner in which the patent granted has been worked either by the original patent holder or a licensee. There is much uncertainty as to what the Patent Office will choose at its discretion to disclose as publication of Form 27. More generally, a considerable amount of uncertainty surrounds the licensing of proprietary technologies in India. On the issue of seed technology, the Supreme Court in May 2018 refused to stay an order by the Delhi High Court which invalidated a patent owned by Monsanto. Monsanto's Indian subsidiary MMLB had licensed the use of the seeds to Nuziveedu Seeds but had subsequently suspended this license in 2015. The seeds continued to be sold by the Nuziveedu Seeds. The Delhi High Court ruled that Monsanto's patent was not enforceable but that the company could seek protection under the Plant Varieties Act. However, such licensed seed traits (in this case bt cotton) are subject to price controls with decisions made on royalties made by the Department of Agriculture under guidelines and licensing requirements issued in 2015-16. In a positive turn, in 2019 the High Court upheld Monsanto's bt Cotton patent, and Monsanto won an arbitration ruling over royalties to be paid by Nuziveedu Seeds. Yet, the Government also further cut Bt Cotton royalties.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.25 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies		Relatively strict price controls are in place for drugs and pharmaceuticals available through the National List of Essential Medicines. Over the last few years price restrictions have been extended to increasing numbers of drugs, including anti-diabetic, cardiovascular and oncology treatments. On a positive note, in 2019 the Government extended the 5-year exemption from price controls in place for local innovative drugs also also to foreign drugs, and fully exempted from control orphan drugs.
R&D tax incentives		India has both a general R&D tax incentive as well as patent box incentive. The R&D tax incentive ranges from a 100% super deduction up to 150% depending on the type of qualifying expenditure and industry sector. Taxpayers engaged in the business of bio-technology or manufacturing or producing products (other than products included on the "negative list") benefit from a super deduction of 150% for in-house R&D expenditure, including capital expenditure (other than land and buildings). In order to qualify the facility where the R&D is conducted must be approved by the Department of Scientific and Industrial Research (DSIR).
Factor 7: Rule of law		Ranked 68th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	48,6
Quality of academic publications, 2015	5,1
Clinical trials per million population to date	2,73
Clinical trials for biologics per million population to date	0,21
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,09
Biotechnology triadic patenting, share of global total average 1999-2013	0,57%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	8,20%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	6,01%
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	72,2
Biofuels production, % of global total, 2017	0.5%

INDONESIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	90 (2009 World Bank)	
Life sciences graduates (PhD & Masters), per million population	0.1 (OECD 2014)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.085 % (2013 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	No RDP term or PTE available. Generally, a very challenging IP environment with heightened patentability standards introduced in 2016 and active use of CLs. Achieved a score of 24.78% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Indonesia provides an abridge review pathway of 150 days (instead of 300) for new drugs or indications approved in more than 3 countries with known good evaluation system; as well as priority review for life-saving drugs. Widespread presence of counterfeit and substandard medicines and weak pharmacovigilance system undermines the integrity of Indonesia's drug supply chain. There are also strong mandatory localization efforts in place.	
Ag-biotech regulations	The Ministry of Agriculture issued the feed safety certificate for GE drought tolerant sugar cane on August 20, 2018 making it the first GE crop to be eligible for commercial cultivation. The Government's GE policy is based on a "precautionary approach" on issues surrounding environmental safety, food safety, and/or feed safety. In addition to sugar cane, a GE corn product is the only one to have undergone assessment for feed, food and environmental safety; however, its possible approval is subject to the implementation of a "monitoring and control" system as required by Government Regulation 21/2015.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0 (score, 0-1)	The technology transfer and licensing environment is heavily influenced by these localization policies and mandates. Technology transfer and commercialization of publicly funded research remains relatively limited. Some state funded universities (including the *Institut Pertanian Bogor* and *Universitas Indonesia*) have clear IP rights policies in place that encourages IP protection. While ownership of the invention remains with the Government and university, at the former researchers and inventors are provided with a guaranteed royalty rate of 40%.
Global Innovation Index 2018, University/Industry collaboration	4.3 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score, 0-1)	An IP Licensing regulation introduced in 2016 (Regulation on Requirements and Procedures for Recordation of Intellectual Property License Agreement, Ministerial Regulation No. 8) requires the registration of license agreements with the relevant authorities for the license to be of legal consequence. Rights-holders must submit the full licensing contract. In addition, relevant IP laws state that licensing agreements include large, general exclusions from license provisions that could harm the economy and hamper technological development in general.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Limited public reimbursement for innovative products. Procurement and tendering favors generics and locally produced products. Multiple challenges exist for innovative products that are included in the national formulary and marketed in Indonesia. No clear methodology exists for their addition to the list or how long they will remain listed. Once listed, they cannot be sold for more than a 50% margin. Under the 2009 Health Law, generic prescription is compulsory within the public health system and packaging must include the generic name. There are considerable barriers to the practical execution of licensing agreements; in particular, to be valid and legally recognized licensing agreements for all major IP rights must be registered with the Indonesian IP authorities.
R&D tax incentives	Limited R&D tax incentives; main incentive is accelerated depreciation and carry-forward of qualifying expenditure. Limited R&D tax incentives; main incentive is accelerated depreciation; sector and geographic restrictions apply. Only R&D activities that are conducted in Indonesia may be claimed as a tax deduction in calculating taxable income.
Factor 7: Rule of law	Ranked 62nd out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	7,8
Quality of academic publications, 2015	3,6
Clinical trials per million population to date	1,66
Clinical trials for biologics per million population to date	0,13
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,06
Biotechnology triadic patenting, share of global total average 1999-2013	0,002%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	19,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	64,3
Biofuels production, % of global total, 2017	2,8%

IRELAND

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	5563 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	76.9 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.1% (OECD 2017)	
BERD spending as a % of total	49% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	69.2 (OECD 2011)	
Biotech R&D as a percentage of BERD	17% (OECD 2011)	
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Achieved a score of 91.88% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High drug regulatory standards through EMA and local Health Products Regulatory Authority.	
Ag-biotech regulations	Ireland announced in 2018 its decision to implement a national ban on GE crops. There is currently no biotechnology cultivation in Ireland with only research taking place.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	The National IP Protocol (first drafted in 2012) was updated in 2016 and provides a framework for companies and Research Performing Organizations on norms for research-related IP agreements. Overall, the Irish tech transfer system is well developed with public-private initiatives taking place at different levels, such as technological centers, larger collaborations such as the Health Innovation Ireland, and support programs such as the Innovation Vouchers, the Technology Gateway Program and the Technology Transfer Strengthening Initiative.
Global Innovation Index 2018, University/Industry collaboration	5 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	According to the Patent Act, changes in ownership or an interest (including license) in a patent or a patent application must be registered, and a copy of the license is required for registration. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Traditionally a generally sustainable pricing and reimbursement environment for biopharmaceutical companies. Yet, Ireland has recently been falling behind in access to new medicines compared to other advanced economies mostly because of delayed reimbursement. Ireland has joined the BeNeLuxA initiative for joint price negotiations, info sharing and policy exchange. The 2013 Health (Pricing and Supply of Medical Goods) Act introduced a system of therapeutic reference pricing that applies to around 1,500 products (although prices are still competitive relative to other European markets). The 2013 Health Act also initiated automatic generic substitution where interchangeability between the generic and reference product has been formally established by the HPRA. Various accompanying initiatives have also been piloted, such as the Medicines Management Program, which identifies a single "preferred drug" within a therapeutic drug class, and accompanies it with prescribing tips for patients and guidelines for doctors.
R&D tax incentives	Tax credits and deductions available for qualifying R&D expenditure; up to 25% of expenditure (Cash refund scheme). Since 2016 patent box incentives reduce corporate tax by 50% IP derived income (a 6.25%t rate instead of 12.5%). An IP amortization regime (tax depreciation for capital expenditure incurred on qualifying IA) is also available since 2009.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	1265,0
Quality of academic publications, 2015	11,1
Clinical trials per million population to date	318,26
Clinical trials for biologics per million population to date	26,59
Early phase (Phase I and II) clinical trials for biologics, per million population to date	5,82
Biotechnology triadic patenting, share of global total average 1999-2013	0,21%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	38,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	79,7
Biofuels production, % of global total, 2017	Negligible

ISRAEL

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	8,250.5 (2012 World Bank)	
Life sciences graduates (PhD & Masters), per million population	119.5 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	4.5% (OECD 2017)	
BERD spending as a % of total	34.7% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	6-yr RDP term available but only for NCEs not biologics; 5-yr PTE available. Achieved a score of 68.84% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High standard biopharma regulatory environment. Israeli MoH relies on the prior approval by a select number of drug regulatory authorities for innovative products, primarily the FDA and EMA. The stated maximum time for approval of innovative products is 270 days (although in practice, challenges remain surrounding registration delays). In 2006 a fast-track registration process was introduced for innovative drugs, setting a 45-day registration deadline for new drugs that are included in the Essential Drug List.	
Ag-biotech regulations	Ag-bio not allowed for commercial production. Sale of imported GE crops is permitted provided a valid Registration Certificate is issued. To date only GE tobacco has received approval. Israel allows development of GE crops for research purposes. In March 2017, Israel decided that genome edited plants with no insertion of foreign DNA are not subject to the GE Seed Regulation.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Technology transfer is well established in Israel, with over 10 tech transfer offices and companies present at the major universities and research institutions for over 50 years. Tech transfer model is similar to the US' Bayh-Dole framework but based on largely independent and corporate-style offices heavily focused on generating royalties and creation of new companies, and has been widely successful. Indeed, two technology transfer offices in Israel, Yissum from Hebrew University and Yeda from the Weizmann Institute, are ranked among the top tech transfer offices worldwide. TTOs are active, with by some estimates an average of 150 new licensing deals, 15 start-ups and NIS1.5 billion (USD400 million) in royalties per year. The Israel Innovation Authority is setting up a second biotech incubator, located in the Northern District.
Global Innovation Index 2018, University/Industry collaboration	5.7 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score, 0-1)	Under the Israeli Corporate Law (1999) and Antitrust Law (1988), licensing agreements between private entities are not required to be disclosed to the Corporate Registrar or the Antitrust authority, except in cases of mergers, and/or if required under court order. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The pricing and reimbursement environment is mixed, in some ways rewarding biopharmaceutical innovation and in other ways putting significant price pressure and eroding reimbursement for cutting edge treatments. For example, within Israel's "basic basket" of health services that are reimbursed within the national health system is a fixed annual budget dedicated specifically to innovative products with a special committee determining regular additions to the basket. Yet at the same time, for other drugs the MoH uses an external reference pricing system to set pharmaceutical prices and price cuts are frequently imposed. A recent reform of the external reference pricing methods for innovative prescription drugs is expected to lead to further price reduction.
R&D tax incentives	Significant R&D incentives in place for biotech, start-ups and targeted R&D. Under the 2017-2018 national budget Israel launched its "Innovation Box" aiming to attract MNCs' operations. incentives include: a lowered corporate income tax of 6% to companies with global turnover of 2.5 billion USD, and 7.5%-12% for companies with lower turnover; a 4% tax on dividends; a capital gains / exit tax for sale of IP of 6% / 12% for companies with over/under 2.5 billion USD.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	1318,1
Quality of academic publications, 2015	10,1
Clinical trials per million population to date	808,73
Clinical trials for biologics per million population to date	50,50
Early phase (Phase I and II) clinical trials for biologics, per million population to date	21,23
Biotechnology triadic patenting, share of global total average 1999-2013	1,12%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	24%
National % share total number of patents from top 50 PCT applicants: universities, 2016	1%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	81,8
Biofuels production, % of global total, 2017	Negligible

JAPAN

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	5210 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3.2% (OECD 2017)	
BERD spending as a % of total	78.3% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	9.69	
Biotech R&D as a percentage of BERD	1.2%	
Factor 3: Intellectual property protection	8-yr RDP equivalent term available and 5-yr PTE available. Achieved a score of 90.46% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High standard biopharma regulatory environment. Recent reform efforts have focused on reducing approval times for innovative products and incentivizing new R&D and clinical trials. The Sakigaki 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.	
Ag-biotech regulations	Science-based and transparent regulations and efficient review process of new events. As of 2018, 319 events had been approved for food use and 139 for commercial cultivation. However, there is still no commercial cultivation of GE food crops in Japan.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Japan introduced a Bayh-Dole framework in 1999 under the Industrial Revitalization Special Law. It covers a range of IP rights, including patents, utility models and seed and seedling registration rights, and similar to the US Bayh-Dole framework allows universities and public research institutions to own IP rights associated with publicly funded R&D. The Prime Minister's 2017 "Strategy for Growth" sets a higher budget for science and technology, with a focus on strengthening public-private partnerships through the Public/Private R&D Investment Strategic Expansion Program.
Global Innovation Index 2018, University/Industry collaboration	4.7 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	Exclusive licenses must be registered at the JPO to be opposable to third parties. On the other hand, non-exclusive licenses and contract-based exclusive licenses require no registration to be effective. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Japan has a highly regulated pricing environment with the Government setting prices and determining whether a drug will be reimbursed in the national health system based on the recommendation of the Central Social Insurance Medical Council. Ongoing price reforms are undermining the Government's commitment to innovation. They add early price review for all prescription drugs, and quarterly for the newest, most expansive and widely used ones; Recent reforms further exacerbates pricing pressure: the Central Social Insurance Medical Council (Chuikyo) significantly restricted access to the Price Maintenance Premium (PMP): new PMP criteria fail to conduct a science-based evaluation and instead rank companies based on the number of recent local trials, drug launches in Japan and 'Sakigake' status, which is acquired i.a. on the basis of having been developed and planned for approval in Japan ahead of other markets. Also, since April 2019 Chuyko implements a new HTA system to retrospectively assess if the premium granted to the drug was justified; the system can result in premium being cut by up to 90%.
R&D tax incentives	Japan has quite a complicated R&D tax credit system that consists of a general, volume-based credit, special credit for R&D carried out with universities as well as an additional available credit available for R&D intensive firms. Volume based credits vary for small and large companies. SMEs can qualify for a credit of 12% of total R&D spending and large companies for an 8-10% credit (which for both should be equal or lower than 25% of the company's corporate tax rate). For SMEs the credit rises to 30% for R&D taking place in partnership with a university or PRO.
Factor 7: Rule of law	Ranked 15th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	833,4
Quality of academic publications, 2015	6,9
Clinical trials per million population to date	42,56
Clinical trials for biologics per million population to date	3,64
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1,85
Biotechnology triadic patenting, share of global total average 1999-2013	14,75%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31,90%
National % share total number of patents from top 50 PCT applicants: universities, 2016	9%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	91,2
Biofuels production, % of global total, 2017	Negligible

KENYA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	225 (2010 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.8% (2010 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Both RDP and PTE are unavailable. Achieved a score of 34% in the International IP Index life sciences Indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The Kenya Pharmacy and Poisons Board (PPB) is in charge of drug regulations. BE/BA studies not compulsory; A pharmacovigilance electronic reporting system has been set up. Biosimilars are not defined but it is generally accepted that where definitions do not exist, the International Conference of Harmonization (ICH), World health Organization (WHO) or the European Union (EU) guidelines can be used as a reference for main definitions. The PPB's Expert Committee on Clinical Trials (ECCT) has developed guidelines to steer through the clinical trial authorization process in Kenya. The review mechanisms for trials is complex with multi-layered committees involved, especially with Kenya Medical Research Institute (KEMRI).	
Ag-biotech regulations	The National Biosafety Authority of Kenya (NBA), established by the Biosafety Act No.2 of 2009, is the main regulatory agency that oversees agricultural biotechnology in Kenya. Since 2009 a policy framework has been put in place covering the most key issues dealing with biotechnology Open trial for GE cotton started in 2018, and cotton is expected to be the first GE product commercially approved for production. Yet, a GE import ban is in place since 2012. In 2016 the National Assembly's Agriculture committee recommended that a new food safety law on GE products be put in place, before the import ban is lifted.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score, 0-1)	Science, Technology and Innovation Act 2013 requires universities and research institutions to have IP policy and TTO. 5 of 45 universities and 3 of 6 research institutes have IP policies in place; 3 universities and 3 research institutes have TTOs/companies; The IP policy of the university of Nairobi assigns ownership to the university. Innovators should be granted 40% of the royalty, 30% to the university, 25% to the Department and 5% to the endowment fund for the IP office. Patentability in universities remains low.
Global Innovation Index 2018, University/Industry collaboration	4.3 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score, 0-1)	All licensing contracts have to be registered, and acts not registered are void. Art 69 of the IP Act on 'Prohibited Terms in Licensing Contract" has a large, protectionist scope. For instance, it precludes import of technology when substantially similar or equivalent technology may be obtained on the same conditions without import.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Medicine prices are not controlled in Kenya, mark-ups in the supply chain are not regulated, and prices are not regularly monitored. The Ministry of Health plans to draft a policy that will ceil prices of essential medicine to boost the country's efforts to achieve universal healthcare by 2022. Local drugs benefits from a 15% price preference in public procurement.
R&D tax incentives	No R&D tax incentives; most tax incentives granted by Kenya focus on manufacturing.
Factor 7: Rule of law	Ranked 101st out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	14,4
Quality of academic publications, 2015	NA
Clinical trials per million population to date	8,95
Clinical trials for biologics per million population to date	1,13
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,74
Biotechnology triadic patenting, share of global total average 1999-2013	0,0005%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	57,6
Biofuels production, % of global total, 2017	Negligible

KOREA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	7113 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	61.96 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	4.6% (OECD 2017)	
BERD spending as a % of total	76.2% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	28.8 (OECD 2015)	
Biotech R&D as a percentage of BERD	2.6% (OECD 2015)	
Factor 3: Intellectual property protection	5-year RDP term available and 5-year PTE available. The Supreme Court recently reversed previous decisions that reduced the scope of PTE to the approved drug product and not to the patented invention itself. This had opened the way to marketing of follow-on patent-infringing products based on a different form of the same ingredient during the extension term. Achieved a score of 78.06% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Korea has a relatively strong clinical and regulatory environment. For biopharmaceuticals the Ministry of Food and Drug Safety (formerly the Korean Food and Drug Administration) is responsible for the authorization and safety supervision of pharmaceuticals. The agency is highly regarded internationally and has been praised by the FDA. Korea introduced a biosimilar pathway in 2009.	
Ag-biotech regulations	After tightening GMO labelling rules earlier in 2017, the country's Rural Development Administration (RDA) has committed "not to promote the production of genetically modified crops" and to shut down its Genetically Modified Crop Development Project; It continued with GE research – approving around 250 research cases for field trials in 2018 – but committed to set up a joint committee with civic groups to hold regular deliberations about GMO research plans. Although significant research is being done, commercialization is delayed and hampered by opposition from local NGOs. Korea plans to review its Living Modified Organism (LMO) Act and launched its 3rd LMO Safety Management Plan in December 2017.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score, 0-1)	Korea early on recognized the importance of closer working relations between universities and businesses and encouraging the commercialization of publicly funded research. Since the early 2000s and the initial interest in developing technology transfer Korea has seen a steady growth in university licensing income and patent rates. Korean biotechnology industry has benefited directly from government-backed tech transfer initiatives through the Law for the Creation and Promotion of the Government Research Institutes enacted in 1999. This program sought to promote technology transfer and the commercialization of biotechnology through start-ups, venture capital partnerships and spin-offs.
Global Innovation Index 2018, University/Industry collaboration	4.4 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	The grant and transfer of an exclusive license have no effect unless they are registered. In other words, an exclusive license does not come into effect if registration process is not completed. An unregistered exclusive license may still have the effect of a proper non-exclusive license. Parties are required to disclose the content of the IP license upon registration.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Korea has in place a strict P&R system applicable primarily to innovative products. Mandatory price cuts have been instituted through a therapeutic reference price system that places innovative and generic drugs in the same baskets, with prices set based on the average price in the basket. The innovative or therapeutic value of a given product is not factored into the price. This system is complemented by other measures including rebates associated with price-volume agreements. Moreover, inclusion for reimbursement is dually determined by a ruling of cost-effectiveness by the Health Insurance Review and Assessment Service and price negotiations with the National Health Insurance Corporation. Most recently Korea has introduced a number of changes to its P&R policies that favor local manufacturers and penalize foreign companies.	
R&D tax incentives	Korea offers R&D tax incentives for both large and SMEs. The incentives are based around incremental and volume-based deductions ranging from 40-50% for qualifying expenditure.	
Factor 7: Rule of law	Ranked 18th out of 126 countries	

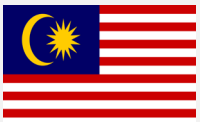
OUTPUTS	
Scientific publications per million population, 2003-2016	924,6
Quality of academic publications, 2015	7,4
Clinical trials per million population to date	192,65
Clinical trials for biologics per million population to date	12,12
Early phase (Phase I and II) clinical trials for biologics, per million population to date	5,17
Biotechnology triadic patenting, share of global total average 1999-2013	2,37%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	42,60%
National % share total number of patents from top 50 PCT applicants: universities, 2016	10%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	76,2
Biofuels production, % of global total, 2017	Negligible

LITHUANIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	2931.7 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	50.93 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.9% (2017 OECD)	
BERD spending as a % of total	39% (2016 OECD)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	18.7 (2015 OECD)	
Biotech R&D as a percentage of BERD	22.16% (2015 OECD)	
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Not included in the International IP Index.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High drug regulatory standards through EMA and local State Medicine Control Agency (SMCA).	
Ag-biotech regulations	Lithuania opted out of GE corn cultivation under the 2015 Directive; even before no GE cultivation took place; the majority of previous Biotech company requests for trials for GM maize, GM oilseed rape and GM potatoes in the country were not given permits by the Environment Ministry.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	Not included	Tech transfer is based on the model of technology parks. Of these, the main is the Sunrise Valley established in 2003 by the Vilnius University, Vilnius Gediminas Technical University, and leading companies in key target sectors. The Sunrise Valley is one of the five integrated science, study, and business valleys established in Lithuania as part of the innovation development programs run by ministries of Economy and Education. Obstacles to tech transfer include low demand for technologies among enterprises and lack of knowledge about technology transfer and IP management.
Global Innovation Index 2018, University/Industry collaboration	4.1 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	Not included	Licenses can be registered at the State Patent Bureau to be opposable to third parties. There is no need to submit the full license document for the purpose of registration. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	Not included	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	IRP is used in the case of both off-patent and patented pharmaceuticals, and the Lithuanian reference price is set at 95% of the average price of the specific medicine in Latvia, Estonia, Poland, the Czech Republic, Hungary, Slovakia, Romania and Bulgaria. If the price of a drug (for which there are at least 3 producers on the market) is more than 10% higher than the reference price, it is disqualified from reimbursement. Price list for reimbursed drugs are updated four times per year to react to reductions in prices in reference markets more quickly. Registration of IP licensing agreements with the State Patent Bureau makes the act opposable to third parties.
R&D tax incentives	Since 2008 Lithuania provides a 200% allowance on the volume of eligible expenditure, with no ceiling in place, with no threshold limiting the amount of eligible R&D expenditure or amount of R&D tax relief. An IP box is also in place.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	698,4
Quality of academic publications, 2015	NA
Clinical trials per million population to date	320,05
Clinical trials for biologics per million population to date	27,23
Early phase (Phase I and II) clinical trials for biologics, per million population to date	7,78
Biotechnology triadic patenting, share of global total average 1999-2013	0,01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	59,5
Biofuels production, % of global total, 2017	Negligible



MALAYSIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	2274 (2015 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.3% (World Bank 2015)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	5-yr RDP term available de jure but de facto exclusivity term much less and limited to global launch; no PTE available. Use of compulsory license ('Government Use License') openly directed at reducing the price of HVC treatment sofosbuvir. Achieved a score of 45.88% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	DRA marked by long processing times for market authorization applications for biopharmaceuticals. While the agency and Ministry of Health have a target of 210 days for market approval industry reports suggest that lengthy delays are not uncommon. Malaysia introduced biosimilar guidelines in 2008 broadly in line with international standards.	
Ag-biotech regulations	Malaysia is approving growing numbers of GE events for import and market release - 36 GE events in 2018 alone. However, there is currently no domestic production of plant biotechnology, and research is minimal. The Malaysian Ministry of Health established mandatory GE labeling guidelines in 2013, which are however not yet enforced.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score, 0-1)	Malaysia does not have in place a specific technology transfer law akin to the U.S. Bayh-Dole framework. Instead, technology transfer at universities and public research institutions is steered by internal guidelines (often developed together with the main funder of the program, the Malaysian government) and two government regulations: the 1999 Government Circular and the 2009 Intellectual Property Policy. While the former by and large vests IP ownership with the Malaysian government, the latter policy vests ownership with the recipient of the relevant funding. As a result, under this policy, publicly funded innovators and creators are able to retain ownership of their creations. Some evidence suggests that patenting rates by Malaysian universities has increased since the introduction of the 2009 Intellectual Property Policy. Some very promising efforts at certain institutions including the *Universiti Putra* Malaysia which has specialized in creating an "Innohub" focusing on creating start-ups and moving researchers into more entrepreneurial roles.
Global Innovation Index 2018, University/Industry collaboration	5.2 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score, 0-1)	The Patents Act does not contain an explicit requirement for the recordal of a license contract. No public policy in place whereby specific components of licensing agreements (eg royalties etc.) need to be disclosed or approved by the Government. However, the actions taken by the Malaysian Government with respect to the threat of a compulsory license for sofosbuvir coerced the manufacturer into seeking a voluntary license. Ultimately this was rejected and a Government use License was issued.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Biopharmaceutical P&R environment is challenging. Reimbursement decisions are often delayed with industry reports suggesting delays of up to five years after regulatory approval. Moreover, there is, for example, no automatic inclusion of products onto the national formulary even if they were developed in Malaysia including through local clinical trials involving local patients. Only drugs included in the National Essential Medicine List are exempted from the 6% Good and Services Tax in force since April 2015.	
R&D tax incentives	Generous and relatively non-discriminatory tax incentives available, both biotech specific and general. The Investment Tax Allowance can take several forms including a 50% tax allowance on capital expenditures for ten years for companies performing in-house R&D and 100% tax allowance on capital expenditures for ten years for R&D service providers. A 200% super deduction on non-capital expenditures is available for companies conducting in-house R&D, donations to research institutes and on the registration of patents, trademarks and licenses overseas if it promotes an exported product. Domestic companies can achieve "Pioneer Status". Companies receiving this designation pay no income tax on statutory income for five years and this benefit can be extended for an additional five years. BioNexus status is available to biotech companies and companies that derive a substantial amount of their final product from biotechnology. Qualifying entities receive a tax exemption on 100% of relevant income for a period of five-ten years (depending on the age of the entity) and a 20% tax exemption after the initial period has expired.	
Factor 7: Rule of law	Ranked 51st out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	321,4
Quality of academic publications, 2015	NA
Clinical trials per million population to date	35,92
Clinical trials for biologics per million population to date	2,31
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,60
Biotechnology triadic patenting, share of global total average 1999-2013	0,04%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	20,20%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	83,1
Biofuels production, % of global total, 2017	Negligible

MEXICO

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	244 (2013 World Bank)	
Life sciences graduates (PhD & Masters), per million population	13.11 (OECD 2014)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.5% (OECD 2016)	
BERD spending as a % of total	20.7% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	0.28 (OECD 2013)	
Biotech R&D as a percentage of BERD	1.1% (OECD 2013)	
Factor 3: Intellectual property protection	5-yr RDP term available but uncertainty over applicability to biologics; no PTE available. Achieved a score of 53.84% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	COFEPRIS has introduced a number of reforms and committed to cutting market authorization times. The agency has been commended for quickly approving medicines that meet urgent local needs, reducing the approval time for drugs already approved in the US, Canada, and EU from 360 days to 60 days. COFERIS approved medications are also approved with less scrutiny in many other South American countries. In 2014 the agency also cut the pre-approval time for clinical trials from 3 months to 1 month reflecting a desire to attract more biopharmaceutical investment and trial activity. Regulatory pathway for Licensing Biotherapeutics approved in 2014 (regulation NOM-257-SSA1-2014).	
Ag-biotech regulations	In 2005, the government passed the Biosafety Law that clarified regulatory issues relating to the research, production and marketing of biotech foods. The Inter-Ministerial Commission on Biosecurity and Genetically Modified Organisms and its subsidiary bodies oversees food related biotech activities. Mexico is one of the countries with the most authorizations for feed and feed use in the world; yet only GE cotton is cultivated. Delays in the release of permits and current legal injunctions have suspended the planting of GE corn and soybeans.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	A decree from Dec 2015 amending the Law on S&T (and the law on Administrative Responsibility of Public servant) aimed to encourage the work of researchers and increase their economic gains. As modified, the S&T law says that governing bodies or their equivalent will approve the guidelines that allow granting researchers, academics and specialized personnel that have generated them up to 70% of the royalties that are generated; and total participation of Public Research Centers cannot exceed 49%. Hence, existing Mexican technology framework is ad hoc and is based largely on the policies in place at the institution receiving public funding. As of 2018, 115 TTOs had been created, and accounted for about 400 to 600 out of a total of 1300 local patents per year on average. Some initiatives are in place to boost tech transfer activities (e.g. National Council of Science and Technology programs) but overall the environment is weak. OECD STI Outlook 2016 assessment of tech transfer Mexico was at the bottom of OECD economies.
Global Innovation Index 2018, University/Industry collaboration	3.6 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	Registration of licensing agreement with IMPI is voluntary. Registration grants right to assert against third parties. Licenses that are not registered will have effect only between the parties. There are no restrictions related to the content of the license agreements.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Mexico has strict price controls in place with maximum retail prices for patented medicines capped by *Secretaría de Economía* (mainly for private sector). Mexico uses an international reference pricing system calculated on the basis of the average ex-factory price of the previous quarter in the six largest markets for a given product globally. Public reimbursement of medicines in Mexico is primarily focused on cost and there are long delays with inclusion. Drug formularies under the major public schemes – *Cuadro Básico y Catálogo de Medicamentos*, *Seguro Popular* and the IMSS drug list – all contain relatively low levels of new, innovative drugs. The majority of products included are generic. Registration of licensing agreements with IMPI is voluntary. Registration grants right to assert against third parties. Licenses that are not registered will have effect only between the parties. No approval of the content of the agreement is required for registration.	
R&D tax incentives	30% R&D tax credit in place since 2017; credits are governed by an interinstitutional government committee and managed by CONACYTT. The R&D activities must take place within Mexico. The maximum amount granted per taxpayer is MX$50 million	
Factor 7: Rule of law	Ranked 99th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	87,0
Quality of academic publications, 2015	3,8
Clinical trials per million population to date	25,61
Clinical trials for biologics per million population to date	2,10
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,58
Biotechnology triadic patenting, share of global total average 1999-2013	0,04%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	37,4%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,05%
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	62,8
Biofuels production, % of global total, 2017	0,00017%

NETHERLANDS

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4842.7 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	101.5 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2% (2017 OECD)	
BERD spending as a % of total	52% (2016 OECD)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available under EU law. Achieved a score of 91.56% on the IP Index life sciences indicators. In 2019 the Patent Law was amended to add a patent exemption for pharmacy preparation.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	High drug regulatory standards upheld through EMA and the Dutch Medicine Evaluation Board.	
Ag-biotech regulations	GE imports are allowed, whereas crop trials and commercial cultivation of biotech crops are effectively prevented by cumbersome regulations. The Netherlands opted out of GE cultivation under the EU directive and is developing its own assessment framework for GE crops cultivation. As a result of the assessment, if cultivation of a crop is allowed in the Netherlands, the government will lift any geographical restriction that may be in place. In 2017 the Netherlands submitted a proposal at EU level on how new breeding techniques (NBTs) could be regulated – based on development of science-based criteria to determine if the crop variety falls under GE legislation.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	The Netherlands has a well-developed national innovation policy including for knowledge transfer and 'valorization' activities. Universities are encouraged to engage in commercialization and actively work with industry to develop new products and technologies. Most major Dutch universities have functioning TTOs and well-developed programs. They have strong links with the business sector, as reflected in a comparatively high share of industry funding for university research and high rate of co-publication. The Universities of Applied Sciences (UAS) perform relatively little and mostly applied research; they play an important role in the provision of innovation skills and have strong links to industry.
Global Innovation Index 2018, University/Industry collaboration	5.6 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	IP licenses need to be registered at the IP Office Register to be valid against third parties. A copy of the licensing agreement needs to be submitted per the EPO. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The Dutch government stopped in 2015 to automatically reimburse new, expensive medicines used in hospitals and instead added centralized reimbursement negotiations with a capped negotiating time. Drugs judged too expensive for immediate inclusion in the basic package are included in the 'lock for expensive medicines' ('Pakketsluis'). Within the 'lock period', the Ministry of Health negotiates price rebates from manufacturers; drugs are marketed but not reimbursed. Since May 2018 the system applies to all patented drugs with an annual cost of EUR50,000 per patient. Besides, past reforms have transferred high-cost in-patient medicines to hospital budgets and capped hospital budgets' growth to an annual rate increase of 1%. Since 2017 the Dutch Government has eyed the use of compulsory licensing to obtain lower prices on expensive drugs. More generally, the Netherlands has been among the most vocal EU Members to question the existing business model for pharmaceutical innovation and the role of patent exclusivity.
R&D tax incentives	Dutch tax law offers both a general R&D tax credit incentive as well as an 'Innovation box' incentive with reduced rates of royalties for IP developed in the Netherlands. The R&D tax credit is available for qualifying expenditure on applied scientific research and the development of new technologies and products. The Dutch Innovation Box provides an effective corporate income tax rate of 7% on ay income derived from qualifying innovations.
Factor 7: Rule of law	Ranked 5th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1 620,3
Quality of academic publications, 2015	14,8
Clinical trials per million population to date	510,6
Clinical trials for biologics per million population to date	36,65
Early phase (Phase I and II) clinical trials for biologics, per million population to date	16,98
Biotechnology triadic patenting, share of global total average 1999-2013	2,07%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	39,40%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	83,3
Biofuels production, % of global total, 2017	2%

NEW ZEALAND

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4052 (OECD 2015)	
Life sciences graduates (PhD & Masters), per million population	67.17 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.2 (OECD 2015)	
BERD spending as a % of total		
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	43.8 (OECD 2015)	
Biotech R&D as a percentage of BERD		
Factor 3: Intellectual property protection	5-yr RDP term of protection and no PTE term in place. Achieved a score of 69.69% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Medsafe provides abbreviated evaluation for applications based on an overseas approval and priority assessment for new medicines based on clinical need, cost savings and export grounds. New Zealand has a relatively efficient ethics approval process for clinical trials (e.g. one of the fastest ethics approval processes in the OECD).	
Ag-biotech regulations	New Zealand applies a heavily regulated and cautious approach to GE products; one product only has been approved for use. Food Standards Australia New Zealand, the regulatory authority for approving the sale of GE; 77 GE food products have been marketed to date. All GE foods sold in New Zealand must be labeled.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Under the Education Act 1987 universities have an obligation to advance, disseminate, and assist in the application of knowledge including commercialization and dissemination. Single universities establish IP ownership rules. The annual report of Kiwinet – the countries network of PROs - mentions few real outcomes from tech transfer activities.
Global Innovation Index 2018, University/Industry collaboration	4.8 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	Patents Act requires the registration of licensing agreements with the Patent Register to be enforceable against third parties; relatively straight forward online registration process. No Government intervention in licensing deals between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	A fixed pharmaceutical budget, with a 2% flexibility buffer, is decided every year to cover major therapeutic areas including vaccines and hospital cancer medicines. An independent agency – PHARMAC – is charged with forecasting the level and cost of demand growth for listed products, and deciding which additional products to reimburse. A pricing system based on negotiations and competitive tendering, coupled with reference prices and spending caps, results in some of the lowest prices among developed markets. Few innovative drugs are funded compared to other high-income countries. PHARMAC cost effectiveness decisions are particularly punitive. Finally, drugs recommended for funding undergo reimbursement delays of 3.5 years on average.
R&D tax incentives	Starting from FY 2019/20, the Government applies a 15% tax credit on eligible expenditure - capped at $120 million per year per business - as R&D tax incentive for business doing R&D in the country.
Factor 7: Rule of law	Ranked 8th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1388,6
Quality of academic publications, 2015	9,8
Clinical trials per million population to date	352,95
Clinical trials for biologics per million population to date	40,05
Early phase (Phase I and II) clinical trials for biologics, per million population to date	14,81
Biotechnology triadic patenting, share of global total average 1999-2013	0,32%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28,80%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	87,2
Biofuels production, % of global total, 2017	Negligible

NIGERIA

INPUTS

Factor 1: Human capital

Number of researchers per million population	38.8 (2007 World Bank)
Life sciences graduates (PhD & Masters), per million population	NA

Factor 2: Infrastructure for R&D

R&D spending % of GDP	0.2% (2007 World Bank)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA

Factor 3: Intellectual property protection

Both RDP and PTE are unavailable. Achieved a score of 29.53% in the International IP Index life sciences indicators.

Factor 4: The regulatory environment

Biopharmaceutical regulations	Drug agency National Agency for Food and Drug Administration and Control (NAFDAC) has improved its standards over the years, but regulations remain poor and counterfeit/substandard drug are an important issue. NAFDAC's registration guidelines foresee a 120-day registration timeline. NAFDAC issued a guideline regarding the regulation of biosimilar products in December 2012 - an overarching guideline covering general considerations for biosimilar approval, such as selection of the reference drug, labelling requirements and fees.
Ag-biotech regulations	National Biosafety Management Agency (NBMA) was established in 2015; trials are being conducted and the first GMO was commercialized in 2018 (Bt Cotton) in a view to revive the country's cotton industry- Yet, the law leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of products with 4% of GE ingredients.

Factor 5: Technology transfer and commercialization frameworks

Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0 (score, 0-1)	The National Office for Technology Acquisition and Promotion (NOTAP) is charged with monitoring the transfer of foreign technology to Nigeria. NOTAP started to set up IP and TTOs in 2006. According to NOTAP website, 43 IPTTOs have been set up. No dedicated legal framework is in place. Yet, NOTAP issued Guidelines on the development of IP for universities and R&D institutions. Also, the National Science, Technology and Innovation Roadmap (NSTIR 2030) covers high utility projects that will be implemented by various institutions and centres of Federal Ministry of Science and Technology in collaboration.
Global Innovation Index 2018, University/Industry collaboration	2.5 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	Nigeria has in place significant barriers to both technology transfer and licensing activities. The National Office for Technology Acquisition and Promotion (NOTAP) oversees all technology transfer and licensing between Nigerian entities and foreign licensors. The agency has the power to evaluate and approve or disapprove technology transfer agreements including evaluating royalty amounts. NOTA, for example, sets and approves royalty rates for all major forms of IP licensing. Royalty rates set vary from 0.5% up to 5% of net sales depending on the technology and type of IP rights. Furthermore Section 23(6) of the Patents and Designs Act provides a broad and unclear remit for the Nigerian Government to cancel any foreign royalty payments and licensing contracts on the ground of national interest and economic development.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Prices are not regulated; In 2017 a WHO price review found that prices – notably procurement prices – were considerably higher than in other African countries. Government tariffs, taxes and distribution mark-ups accounting for a significant proportion of the final price. Introduction of a 20% 'Import Adjustment Tax' exacerbated the effect of currency devaluation on drug prices.
R&D tax incentives	Companies engaged in R&D activities for commercialization are allowed 20% investment tax credit on their qualifying expenditure for that purpose; Nigeria's corporate tax rate is 30%, but when investments take place in specific sectors that involve R&D, a tax holiday will be granted ranging from three to five years.
Factor 7: Rule of law	Ranked 106th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	15,4
Quality of academic publications, 2015	NA
Clinical trials per million population to date	0,81
Clinical trials for biologics per million population to date	0,04
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,02
Biotechnology triadic patenting, share of global total average 1999-2013	0%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	50,1
Biofuels production, % of global total, 2017	Negligible

NORWAY

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	6073 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	76.5 (2016 OECD)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2.1% (2017 OECD)	
BERD spending as a % of total	43.2% (2016 OECD)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	38.45 (2016 OECD)	
Biotech R&D as a percentage of BERD	6.1% (2016 OECD)	
Factor 3: Intellectual property protection	Both 10-yr RDP term available and 5-yr SPC available, as Norway aligns its standards to EU legislation. Not included in the International IP Index.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	As a Member of EEA, marketing approval of pharmaceuticals in Norway is subject to EU regulations. They can either be approved EU-wide by the EMA in the Centralized Procedure, or locally in the Decentralized Procedure, Mutual Recognition Procedure, or National Procedure by the Norwegian Medicine Agency (NoMA); also EMA biosimilar approval pathway applies. Biosimilar switching at discretion of hospitals/physicians.	
Ag-biotech regulations	Norway enforces a restrictive policy on GMO. No GE product is grown or imported in Norway due to the Gene Technology Act, a strict legislation that lead to rejection of approval of products marketed in the EU.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	Not included	Since 2003 universities are granted ownership of IP rights which previously belonged to individual researchers. As part of these legislative changes, the universities were assigned explicit responsibility for commercialization of research, with limited coordination from the Norwegian Government Norway's program on the commercialization of R&D results (FORNY) was established in 1995 and has become the main instrument for supporting the commercialization of results from Norwegian research institutions receiving a steadily increased budget. FORNY funds the Norwegian technology transfer offices (TTOs) and projects in need of proof-of-concept.
Global Innovation Index 2018, University/Industry collaboration	4.8 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	Not included	Patent and trademark licenses have to be notified to the Norwegian Industrial Property Office (Patentstyret) to be enforceable vis-à-vis third parties.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	Not included	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	NoMA is charge for both approval and reimbursement. The agency requires all manufacturers to apply for a maximum pharmacy purchase price (PPP) for each prescription medicine, regardless of whether they seek reimbursement or not. Maximum prices are based on the average of the three lowest in 9 countries (Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden, and the UK). Norway also carries out therapeutic-wide tenders for which minimum discount levels have been decided in advance. Regional health authorities commonly base prescribing recommendations and formulary guidance around the lowest-cost medicines in a therapeutic group. Finally, Norway participates in several cross-country negotiation and procurement initiatives for innovative medicines that include Iceland, Sweden, and Denmark. HTA is mandatory for reimbursement decision. Reimbursed medicines are included on a positive list called the "blue list".
R&D tax incentives	Volume based R&D tax credit (SkatteFUNN R&D tax credit), with a headline credit rate slightly larger for SMEs (20%) than other companies (18%); eligible expenditures ceiled to NOK 25 million (USD 2.9 million) for in-house R&D and to NOK 50 million (USD 5.8 million) for the sum of in-house R&D and R&D purchased from research institutions. The estimated volume of the tax incentive was NOK 4.3 billion (USD 0.5 billion) in 2017.
Factor 7: Rule of law	Ranked 2nd out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1 641,2
Quality of academic publications, 2015	11,1
Clinical trials per million population to date	683,24
Clinical trials for biologics per million population to date	41,84
Early phase (Phase I and II) clinical trials for biologics, per million population to date	13,63
Biotechnology triadic patenting, share of global total average 1999-2013	0,39%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	47%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	83
Biofuels production, % of global total, 2017	Negligible

PERU

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	NA	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.12% (UNESCO-UIR 2017)	
BERD spending as a % of total		
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	5-yr RDP term of protection, not covering new uses and indications. Although legislation does allow for protection of biologics, the government has taken the position that biologics are not included under this regime. No PTE. Achieved a score of 39.94% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Regulatory barriers, processing delays and duplicative testing requirements create hurdles to product registration. Capabilities of the MoH General Direction of Medicines, Supplies and Drugs (DIGEMID) need to be increased to reduce current uncertainty and unpredictability.	
Ag-biotech regulations	Peru's implements since 2011 a 10-year moratorium on GE crops and a zero tolerance for GE events. The Ministry of Environment tests conventional imported seed shipments upon arrival, raising concerns amongst seed traders. The detection of a GE event in seeds, including adventitious presence, results in steep fines.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0 (score, 0-1)	According to art 53 of the University Law (N. 30220) ownership remains with the university, which is entitled to at least 20% royalties. Nascent tech transfer framework, with limited TT capacity/patenting activity. CT activities are financed under the Peru Innovate program and SCIENCACTIVA (the agency in charge of the National Fund for STI) but are mostly based at increasing number of researchers. According to INDECOPI, in 2015 universities registered 63 patents (and business 52). A special Plan for Tech Transfer 2016-2021 was issued with the goal of enhancing industry's competitiveness and productivity through tech transfer and enhanced IP protection.
Global Innovation Index 2018, University/Industry collaboration	2.9 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	Art 7 Legislative Decree 1075 of 2009 states that registration of IP license is not mandatory, and affects validity against third parties only for patents, not trademarks. Yet, ANDEAN decision 291 adds significant restrictions on agreements with foreign licensors, requiring registration and evaluation of licenses by national authorities on the basis of subjective criteria regarding the so-called value of imported technologies.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.25 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	No direct price controls of pharmaceuticals. Public insurers cover the majority of products on the National formulary and essential medicines list (*Petitorio Nacional Unico de Medicamentos Esenciales* - PNME), but not necessarily other products. PNME is largely made up of generics. DIGEMID is considering parallel import of cancer drugs to bring down prices. Sharing of price info with Pacific Alliance countries.
R&D tax incentives	The law on Fiscal Incentives to Innovation (Law 30309) creates special deduction regime for projects related to scientific research, technological development, and technological innovation as of 2016. According to this incentive, taxpayers investing in these projects will be able to deduct 150% or 175% of the expenses incurred.
Factor 7: Rule of law	Ranked 70th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	15,9
Quality of academic publications, 2015	NA
Clinical trials per million population to date	29,78
Clinical trials for biologics per million population to date	3,54
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1,21
Biotechnology triadic patenting, share of global total average 1999-2013	0,0002%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	20%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	53,2
Biofuels production, % of global total, 2017	Negligible

PHILIPPINES

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	187.7 (2013 World Bank)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.1% (2013 World Bank)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Both RDP and PTE unavailable. Achieved a score of 32.5% on the International IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The Philippines's FDA implemented in the second half of 2018 a one-time automatic sign off of all compliant applications pending for more than 6 months to tackle the long drug approval backlog (around 80,000 drug applications); Biosimilar pathway adopted in 2014 (along WHO guidelines); Bioequivalence requirement for all generics in place since 2014.	
Ag-biotech regulations	The National Committee on Biosafety of the Philippines (NCBP) was created by Executive Order 430 in 1990; the Philippines has since then a well-established, science-based framework for GE product approval; In 2003 it was the first Asian country to allow the planting of a GE crop (Bt corn). A Joint Departmental Circular adopted after 2012 provides more consideration to socio-economic issues and environmental impacts during approval.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score, 0-1)	The Technology Transfer Act 2009 grants ownership of IP rights derived by public funded research to the research entity; and foresees that the researchers should receive no less than 40% of IP revenues. and grants to R&D institutions are regarded as mostly disconnected from the needs of industry. IPOPHIL has created an IP academy to help universities translate their knowledge into usable technology.
Global Innovation Index 2018, University/Industry collaboration	3.5 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	Non-recordation does not affect the validity nor the enforceability of an agreement. However, parties must ensure the provisions in the agreement comply with some limitations detailed in the IP code; non-compliant agreement are non-enforceable. Amendments to the IP code would make registration needed for the license to be valid. To make sure that licenses comply with the terms of the IP code, the parts may demand a pre-clearance analysis from the IP office - IPOPHIL (7 to 10 days); they can also request to be exempted from compliance: if exemption is granted, they are then added to a register. Hence, the register keeps a record and therefore justifies non-compliant tech transfer agreements.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.25 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Capped procurement prices (Drug Price Reference Index) and large discounts for segments of the population (seniors, disabled). The Government is in the process of establishing a price control mechanism for all prescription drugs based on external reference pricing. Unclear criteria for reimbursement and procurement preference to national bidders; offset program for public procurements of imported goods.
R&D tax incentives	Provisions on deductibility of R&D expenditures have been in force since the early 1990s: expenditures can be treated either as ordinary and necessary expenses deductible from gross income at 100% or as deferred expenses ratably distributed over a period of at least 60 months. The TRAIN tax reform adopted in 2018 foresees a preferential income tax rate of 15% on taxable income plus an additional double deduction for R&D related to the registered activities identified and approved as such by the appropriate Government agencies.
Factor 7: Rule of law	Ranked 90th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	7,3
Quality of academic publications, 2015	NA
Clinical trials per million population to date	8,79
Clinical trials for biologics per million population to date	1,53
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,42
Biotechnology triadic patenting, share of global total average 1999-2013	0,002%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	31,8%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,32%
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	61,3
Biofuels production, % of global total, 2017	Negligible

RUSSIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	2979 (2016 World Bank)	
Life sciences graduates (PhD & Masters), per million population	30.45 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.1% (OECD 2017)	
BERD spending as a % of total	30.2% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	0.94 (OECD 2017)	
Biotech R&D as a percentage of BERD	0.53% (OECD 2017)	
Factor 3: Intellectual property protection	6-yr RDP term available but uncertainty over actual availability e.g. 2016 IP Court ruling; 5-yr PTE available. Achieved a score of 43.5% on the IP Index life sciences indicators. Russian courts have granted and upheld a compulsory license for an American cancer drug.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	For biopharmaceuticals key challenges include lack of GMP enforcement, quality control (e.g. presence of counterfeit and substandard medicines) and localization requirements. Pharma 2020 includes clear targets for local production, including 50-70% of domestic drugs on the total pharmaceutical market (in 2012 the share was about 20%), 60% of patented medicine market in terms of value by local companies and 85-90% of the medicines on Russia's Essential Drug List (EDL). Amendments to the Law 'On Circulation of Pharmaceuticals' approved May 2018 removes the requirement of local GMP inspections.	
Ag-biotech regulations	Since 2016 Russia bans cultivation and breeding of genetically engineered (GE) plants and animals. While imports of GE products are permitted, currently there are no methodological guidelines for registering GE events making registration and at times also import impossible. There is a mechanism for registration of GE products for food use.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	Central legislative framework for technology transfer focuses on enterprise partnerships as opposed to patenting and licensing agreements. Federal Law 217-FZ on the Commercialization of University Research (2009) provides universities with the exclusive right to market their research through launching their own SMEs or obtaining stock in companies that rely on their research. Specifically, Law N. 217 requires that universities have at least a 25-33% share in spin-offs, depending on the type of company, in exchange for the right to use the university invention. Looking at outputs patenting by Russian institutions is relatively low as is tech transfer activities at universities. Overall technology transfer efforts are hampered most notably by localization barriers including local data storage requirements, manufacturing and local production requirements (e.g. for pharmaceuticals and clinical trials).
Global Innovation Index 2018, University/Industry collaboration	3.9 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	Registration of all licensing transactions for registered IP rights is required; without registration such licensing contracts are unenforceable. The Federal Antimonopoly Service (FAS) has very narrow interpretation of abuse of dominance and has in several cases imposed itself into licensing and distribution deals.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Prices of medicines included in the EDL are subject to control on three levels (manufacturer, wholesaler and pharmacy prices) and by a process of registration of maximum manufacturer price and by wholesaler and pharmacy markup limitations (varying by region). The EDL, which is the basis for reimbursement in the hospital segment and the reference for regional formularies, is updated infrequently limiting reimbursement for medicines recently approved for market. In October 2018 Russia reduced the maximum selling prices of 1043 previously vital and essential medicines by an average 43%, following an international comparative analysis of prices based on the minimum selling prices in various markets worldwide conducted by the anti-monopoly authority (FAS). In parallel, the Russian Ministry of manufacturers to revise registered prices of medicines in the event of their reduction in the reference countries.	
R&D tax incentives	Russia offers a generous 150% R&D tax deduction on qualifying expenses. This is available generally as well as for targeted industries. In addition, entities operating in Special Economic Zones (such as the Skolkovo Innovation Centre) may qualify for additional tax credits and benefits.	
Factor 7: Rule of law	Ranked 88th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	259,8
Quality of academic publications, 2015	4,8
Clinical trials per million population to date	30,54
Clinical trials for biologics per million population to date	3,12
Early phase (Phase I and II) clinical trials for biologics, per million population to date	1,11
Biotechnology triadic patenting, share of global total average 1999-2013	0,26%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	14,30%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	63,5
Biofuels production, % of global total, 2017	Negligible

SAUDI ARABIA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	NA	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.082% (2013 UNESCO-UIS)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Clear 5-yr RDP term in place. Some reports indicate follow-on products have been approved through indirect reliance. No PTE offered. In 2017, the SFDA effectively overrode Saudi Arabia's linkage regime by approving for market a follow-on product to Daclatasvir. Achieved a score of 40.34% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Saudi FDA viewed as being a high standard DRA comparable to Singapore, Canada etc. New fast-track verification route for product approval implemented in 2017.	
Ag-biotech regulations	Saudi regulations allow the importation and planting of biotech seeds under strict conditions. Also, strict labeling requirements (if more than 1% of ingredients is GE). There is currently no commercial cultivation of ag-bio products.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score, 0-1)	Technology transfer has been a key part of Saudi Arabia's science and technology framework since the early 2000s and the 2002 National Policy for Science and Technology. There are several key initiatives most notably the government-owned Technology Development and Investment Company that is tasked with developing and launching industrial opportunities aligned with the national research center priorities as Joint Ventures with international technology companies. There is also the 2014 Saudi Arabia Advanced Research Alliance a public-private collaboration among the main entities working on innovation (KACST, TAQNIA, KAUST KFUPM and RTI International) aimed at supporting commercialization of new technologies. Saudi Arabia is one of the few emerging markets whose universities are among the top-50 globally in terms of PCT patent applications.
Global Innovation Index 2018, University/Industry collaboration	3.7 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	Both the Patent Act and Trademark Act require the registration of a "contractual license" for it to be valid against third parties. Detailed contractual terms must be disclosed and reviewed by the Patent Office which reserves the right to amend the license contract.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Pricing environment based on IRP. Basket of countries frequently includes low-income economies with substantially lower per capita income than Saudi Arabia. Maximum prices based on lowest price in basket of comparable countries. BCI Survey results 2016 suggest that pricing policy lacks transparency and predictability.
R&D tax incentives	No statutory R&D tax incentives in place. Some R&D grants made directly by KAUST.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	138,6
Quality of academic publications, 2015	NA
Clinical trials per million population to date	18,91
Clinical trials for biologics per million population to date	0,73
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,18
Biotechnology triadic patenting, share of global total average 1999-2013	0,01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	13,70%
National % share total number of patents from top 50 PCT applicants: universities, 2016	2%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	64,3
Biofuels production, % of global total, 2017	Negligible

SINGAPORE

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	6,729 (World Bank 2014)	
Life sciences graduates (PhD & Masters), per million population	150.74 (Singapore Statistics 2017)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	2.2% (OECD 2014)	
BERD spending as a % of total	54.1% (OECD 2014)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Clear 5-yr RDP and PTE term in place. Achieved a score of 80.44% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Health Sciences Authority is highly regarded and is involved in the regulation of Western medicinal products as well as Chinese proprietary medicines and cosmetic products. Circa 80% of marketing applications approved through an abridged route relying on evaluations from leading drug regulatory agencies in other countries. Under this route the approval time is on average just 60-180 days (depending on the number of external evaluations available). An additional priority review path is also available for certain life-threatening conditions with limited treatment options, which further reduces approval time to 60 days.	
Ag-biotech regulations	GM foods are regulated by the Genetic Modification Advisory Committee. Singapore's regulations are science-based and the registration process is generally viewed as efficient. As of October 2018, 35 GE plant products have been approved for use as food or food ingredients. No specific labelling regulations. Regulatory and ethical issues arising from innovative biotechnologies are being considered by regulators.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Singapore has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. Biotech/pharm specific transfer activities include the Biomedical Sciences Industry Partnership Office that liaises between universities, public research institutes and industry. Singapore's main bio clusters host domestic and international firms, biomedical research institutions and are also integrating governmental R&D bodies. Technology transfer is also being promoted and is made accessible by the close proximity of these bio clusters to the Singapore Science Park and the National University.
Global Innovation Index 2018, University/Industry collaboration	5.3 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	Licenses for all major IPRs can be recorded (Patents Act outlines this for patent, article 41-43). Failure to register a license does not in itself mean that the license is unenforceable. However, registration does results in stronger and clearer protection. No direct Government intervention in licensing terms.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The biopharmaceutical market is relatively free with government subsidies in place only for pharmaceuticals included on the Standard Drug List (though this covers the majority of drugs prescribed). Products may be added to the list on an annual basis. Under the scheme, "essential" or first-line drugs are the most heavily subsidized, with patients covering just SGD1.40 per item per week. For relatively more expensive essential drugs patients pay 50% of the sales price. Drugs not included on the list are priced based on the market. Additional concerns over access are addressed through financial assistance schemes, such as the special chronic disease insurance program.
R&D tax incentives	Singapore offers an R&D tax credit of up to 400% on qualifying R&D expenditure, but subject to a cap. The majority of this relief is available on R&D performed in Singapore. Singapore also has an "angel investors tax deduction" program that provides a tax deduction for 50% of the investment amount. There is also plans for introducing an OECD BEPS compliant IP incentive provisionally called the "Intellectual Property Development Incentive".
Factor 7: Rule of law	Ranked 13th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1666,5
Quality of academic publications, 2015	NA
Clinical trials per million population to date	391,11
Clinical trials for biologics per million population to date	26,01
Early phase (Phase I and II) clinical trials for biologics, per million population to date	11,94
Biotechnology triadic patenting, share of global total average 1999-2013	0,42%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	25,50%
National % share total number of patents from top 50 PCT applicants: universities, 2016	1%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	90,7
Biofuels production, % of global total, 2017	Negligible

SOUTH AFRICA

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	472.1 (World Bank 2015)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.8% (World Bank 2015)	
BERD spending as a % of total	38.9% (OECD 2015)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	Neither RDP term of protection nor PTE term in place. Achieved a score of 31.81% on the IP Index life sciences indicators. New IP Policy approved in 2018 expands the use of TRIPS flexibilities, raises the bar to receive patent protection and introduces substantive search and examination.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	A primary challenge has been long approval delays for biopharmaceuticals. The South African Health Products Regulatory Authority (SAHPRA) finally started to work in February 2018 with a broader mandate than the Medicines Control Council, which includes registration and control of medical devices, in vitro diagnostics, and complementary medicines. The new watchdog has announced the use of external experts and definition of reliance pathways as ways to tackle the large approval backlog.	
Ag-biotech regulations	South Africa is a global leader and major producer of ag-bio crops with a clear regulatory framework in place. The 1997 GMO Act and the 2011 Consumer Protection Bill regulate the production and consumption of GE food.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	South Africa introduced a modern technology transfer framework in 2008. The "Intellectual Property Rights from Publicly Financed Research and Development Act" established the parameters by which publicly funded research can be commercialized and, crucially, where ownership over the generated IP resides. The stated purpose of the Act has been to stimulate research and the commercialization of publicly funded research. Broadly speaking the Act and its accompanying regulations establish the principle that the recipient will retain IP generated through publicly funded research.
Global Innovation Index 2018, University/Industry collaboration	4.4 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	The use of licensed technology is hampered by a number of localization components and ill-defined restrictions and geographical limitations. For instance, the Government retains the right to use the technology royalty free " for the health, security and emergency needs of the Republic".
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.25 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	P&R system both directly and indirectly prioritizes generic drugs, primarily through a new external referencing pricing system that favors low cost drugs and generic substitution policies. Since 2005 biopharmaceutical prices have been capped at a rate in line with inflation, which for imported medicines is typically considered to be under value in relation to the exchange rate. On top of this, in 2015 a de facto external referencing price mechanism was introduced for innovative drugs. Under the new regulation innovative manufacturers will have to provide the price of their drugs in Australia, New Zealand, Spain and Canada (or, if not present in these markets, in all the countries they are sold) and the DoH will reportedly request companies to forego the yearly price increases if the price applied in South Africa is higher than these reference prices.
R&D tax incentives	South Africa offers relatively generous R&D tax benefits including a 150% super deduction for R&D expenditures subject to pre-approval by a government-appointed approval committee. It also offers accelerated depreciation for capital expenditures incurred to develop or construct assets used in R&D activities (40% for the first year and 20% in the three years after for infrastructure built after 2012).
Factor 7: Rule of law	Ranked 47th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	140,6
Quality of academic publications, 2015	7,1
Clinical trials per million population to date	45,95
Clinical trials for biologics per million population to date	4,85
Early phase (Phase I and II) clinical trials for biologics, per million population to date	2,19
Biotechnology triadic patenting, share of global total average 1999-2013	0,06%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28,80%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	1,42%
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	64,8
Biofuels production, % of global total, 2017	Negligible

SWEDEN

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	7153.4 (World Bank 2016)	
Life sciences graduates (PhD & Masters), per million population	67.9 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3.3% (OECD 2017)	
BERD spending as a % of total	57.3% (OECD 2015)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	49.7 (OECD 2015)	
Biotech R&D as a percentage of BERD	4.6% (OECD 2015)	
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Achieved a score of 94.91% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The 2015 Medicinal Products Act regulates the production, registration and distribution of drugs. The Swedish Medical Product Agency (*Läkemedelverket*) commits to take marketing approval decisions within 210 days from the filing of the application; The Medical Products Agency issued a National Pharmaceutical Strategy 2016-2018, a collaborative effort to ensure equal access, safe and effective use and environmental sustainability of drugs.	
Ag-biotech regulations	The government has implemented a system whereby every use should be judged on its own risks and merits. Chapter 13 of the Swedish Environmental Code regulates all use of GMOs. Sweden was one of six EU countries to conduct open field tests in 2017; cultivation is allowed but no GE corn is grown; Sweden has adopted legislation that explicitly prohibits 'GE-free' labeling; however, the government is increasingly pressured by public negative opinion on GMOs.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	The Act regarding the right to employee inventions and its university employee exemption became law in 1949, and is still in force. The law establishes the professor privilege. Swedish university employees retain the exclusive right to all patentable inventions. Swedish TTOs are located in the eight largest universities and are partly funded by a government support program. Government funding requires that the eight TTOs also take a regional responsibility serving also smaller universities and colleges in the region. Each university also has a holding company that can invest into university spin-off. These university holding companies have limited investment funds that often make them work with investors, private and other state investment companies. The life science cooperation program brings together industry, academia and public institutions through regular meetings since 2015. The priority areas of the cooperation program include a common technical standard and semantics for faster dissemination of knowledge and development of products and services. Sweden's innovation agency VINNOVA supports a national pilot project to develop Swedish science parks as regional nodes in the national innovation system. State new venture capital company – Saminvest – launched July 2017 with the task of investing in privately-managed venture capital funds, where there is a need for market-compliant investments.
Global Innovation Index 2018, University/Industry collaboration	5.2 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score, 0-1)	Registration of license agreements is not required for them to take effect. Where licenses are recorded an extract from the relevant agreement is accepted by the Swedish Patent Office. No Government intervention in licensing terms between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	The Board of Pharmaceutical Benefits within the Dental and pharmaceutical benefits agency (TLV) decides simultaneously on pricing and reimbursement for new drugs to be included in the benefits scheme. The decision is based on clinical evidence and health economic documentation provided by pharmaceutical companies. TLV collaborates with the Swedish Agency for Health Technology Assessment and Assessment of Social Services for health economic assessment. TLV and the 21 county/region councils (responsible for drug procurement and for issuing a list of drugs to be used as first choice treatments) negotiate prices with drug companies. The reimbursement decision depends on several factors, where one may be the existence of a managed entry agreement between the county councils and the pharmaceutical company. Also, managed entry agreements between pharmaceutical companies and county councils include growing payback amounts. The pricing system is reportedly complex, and a pricing reform is ongoing to tackle these complexities; the reform is considering introducing a state fund dedicated to new innovative drugs.	
R&D tax incentives	R&D tax incentives are offered in the form of reduced social security contributions for R&D employees engaged in commercially performed R&D.	
Factor 7: Rule of law	Ranked 4th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	1806,6
Quality of academic publications, 2015	12,5
Clinical trials per million population to date	563,58
Clinical trials for biologics per million population to date	37,25
Early phase (Phase I and II) clinical trials for biologics, per million population to date	13,81
Biotechnology triadic patenting, share of global total average 1999-2013	1,55%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	38,90%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	NA
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	83,3
Biofuels production, % of global total, 2017	0,2%

SWITZERLAND

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	5257.3 (World Bank 2015)	
Life sciences graduates (PhD & Masters), per million population	134.2 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3.4% (OECD 2015)	
BERD spending as a % of total	63.5% (OECD 2015)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	378.3 (OECD 2015)	
Biotech R&D as a percentage of BERD	30.2% (OECD 2012)	
Factor 3: Intellectual property protection	10-yr RDP term of protection in place and 5-yr PTE term in place. Achieved a score of 92.19% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Stringent DRA and high-quality biopharmaceutical regulations including biosimilars pathway.	
Ag-biotech regulations	No regulatory framework for ag-bio; national ban on GM foods.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	Switzerland has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. The Commission for Technology and Innovation has as one of its core goals to promote technology transfer between universities and industry including the Swiss Biotech association. It does so through innovation mentors providing support in drawing up project applications as well as interactive and physical platforms. Academic institutions and professionals have their own technology transfer association through swiTT (Swiss Technology Transfer Association). Swiss institutions have a high rate of patenting intensity and activity.
Global Innovation Index 2018, University/Industry collaboration	5.8 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	Licenses can be recorded in the Patent Register. Recordal of license is not required by law but provides a stronger basis for third party oppositions. No direct government intervention in licensing agreement.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Relatively strict pricing policies are in place for drugs and pharmaceuticals available through basic insurance. There are consequently a limited number of market incentives for these products, which total over 2,500 medicines. However, for both supplementary insurance and all medicines not listed on the public reimbursement list there is free pricing and a relative free market.
R&D tax incentives	New tax reform package passed in June 2016 includes significant changes to R&D incentive structures. Package includes a "cantonal patent box" according to which IP-generated income would be exempted up to 90% on cantonal and communal taxes. Package also includes a potential 150% R&D super deduction.
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	2205,4
Quality of academic publications, 2015	15,3
Clinical trials per million population to date	719,94
Clinical trials for biologics per million population to date	50,79
Early phase (Phase I and II) clinical trials for biologics, per million population to date	21,97
Biotechnology triadic patenting, share of global total average 1999-2013	2,06%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	44,4%
National % share total number of patents from top 50 PCT applicants: universities, 2016	1%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	82,2
Biofuels production, % of global total, 2017	Negligible

TAIWAN

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	7996 (Taiwan Ministry of Science and Technology 2017)	
Life sciences graduates (PhD & Masters), per million population	192.3 (Taiwan Ministry of Science and Technology 2017)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	3.3% (OECD 2017)	
BERD spending as a % of total	79% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	37.64[1] (Taiwan Ministry of Science and Technology 2017)	
Biotech R&D as a percentage of BERD	6.11% (Taiwan Ministry of Science and Technology 2017)	
Factor 3: Intellectual property protection	5-yr RDP term of protection in place and 5-yr PTE term in place. Achieved a score of 64.41% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Taiwan's DRA is viewed as quite strong adhering to international regulatory standards; however, there have been long delays in product approvals. Japan and Taiwan have launched a pilot Project expected to accelerate new drug reviews in Taiwan by using Japan's Pharmaceutical and Medical Devices Agency's review reports.	
Ag-biotech regulations	There is no commercial cultivation of biotechnology products. Taiwan is a significant importer of GM corn, cotton and soybeans from the US and Brazil. Labeling is required on some products but generally the regulatory framework is science based.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.75 (score, 0-1)	The Basic Law on Science and Technology introduced in 1999 establishes a Bayh-Dole style framework for tech transfer such that publicly funded IP rights and technologies are fully owned by public institutions. At the same time, the government promoted patenting and licensing as a means of university and PRI income by reducing other types of funding for universities or by matching any revenue gained from the private sector. Significant resources are dedicated to training IP management and commercialization for universities and SMEs. Taiwanese universities and research institutes are known for strong patenting rates as well as generating substantial income from royalties and license fees. Rates of patents registered by the Industrial Technology Research Institute (IRTI, the largest public research institute) with the USPTO and co-owned by either a university or firm rising more than eight times between 2002 and 2012.
Global Innovation Index 2018, University/Industry collaboration	Not Included	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	The licensing or sub-licensing of IP does not require a written form, can be based on an implied agreement, and does not need to be recorded with the TIPO. However, such licensing or sub-licensing will have no effect against a third party unless it is recorded with the TIPO.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	

[1]This value includes both business and public biotech R&D expenditure.

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	National Health Insurance pricing is considered a significant challenge, involving annual drug price and spending targets and delays in approval of reimbursement, especially for innovative products.
R&D tax incentives	Taiwan offers a tax credit of 15% of R&D expenditures applied in one year or a tax credit of 10% over three years. The tax credit is offset R&D from payable for the current year, and may not exceed 30% of profit-seeking enterprise income tax due for the current year. For biotechnology and new pharmaceutical companies, 35% of R&D and employee training expenditures may be claimed as a deductible expense against the current year's payable business income tax. Royalties paid on qualified patent rights are exempted from withholding tax provided a certain sets of criteria are met
Factor 7: Rule of law	Not included

OUTPUTS	
Scientific publications per million population, 2003-2016	1 097,7
Quality of academic publications, 2015	NA
Clinical trials per million population to date	253,66
Clinical trials for biologics per million population to date	14,55
Early phase (Phase I and II) clinical trials for biologics, per million population to date	5,05
Biotechnology triadic patenting, share of global total average 1999-2013	0,38%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	28,3%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	76,9
Biofuels production, % of global total, 2017	Negligible

THAILAND

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	965.4 (World Bank 2015)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	0.63% (World Bank 2015)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	No RDP term of protection or PTE term in place. Achieved a score of 30.38% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Real quality concerns and lack of regulatory resources. To address this lack of resources, the Prime Minister issued Order No. 77/2559 in 2016 which allows the FDA to re-invest its revenues to improve the approval process (new official fee structure unveiled Nov 2017) and outsource some of its work; Lack of enforcement of GMP requirements and self-regulation of GPO entity.	
Ag-biotech regulations	De facto ban in place on GM crop cultivation with no field trials allowed and no commercial sale of GE products. Ag-bio regulatory framework (Draft Biosafety legislation) remains in limbo. Thailand is looking to adopt a positive list of approved GE events for food products.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score, 0-1)	Thailand's innovation infrastructure fundamentally being reformed in 2017. IP Commercialization Law allows transfer of IP ownership from funding agencies to grantees. Existing technology and commercialization efforts are primarily based in the National Science and Technology Development Agency, the main national PRO. The Agency has a relatively extensive patent portfolio and partners with industry, universities and other research institutes in Thailand. Mahidol University – the main university for medical studies – has an established tech transfer system in place; yet, overall, the operation of TTOs in universities is judged bureaucratic and inefficient A recent proposal allows foreign universities to establish local branches in Thailand's special economic zones, a move expected to increase quality of available human resources.
Global Innovation Index 2018, University/Industry collaboration	3.9 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0 (score, 0-1)	Patent licenses must be registered with the Department of Intellectual Property or else be void. Draft Patent Act amendments would turn the requirement to register a patent license agreement into a recordation system with the Patent Office. The Director General of the Department of Intellectual Property can apply a rule of reason type analysis on these clauses to determine if there is an unauthorized unfair restriction.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Traditionally for the biopharmaceutical sector the key challenge has been the favored status of local state supplier GPO. GPO is the dominant local pharmaceutical producer and supplier, and has long been given preferential treatment in the public procurement system, both on the basis of procurement rules which require public hospitals to make 60% of purchases from the GPO as well as the government's "Median Price" scheme in which prices are arbitrarily determined in favor of the GPO price or lowest local generic price. Under the new Public Procurement Act enacted in 2017 the GPO gained additional responsibilities for the procurement of pharmaceutical product. Regarding reimbursement in order to obtain reimbursement within the public health system it is necessary to be listed on the NLED. However, the NLED is structured such that it is impossible to achieve listing if a generic or therapeutic equivalent is available. The list includes around 1,400 products, of which only 16 belong to the E2 subcategory for innovative ("high-cost") drugs. Even for products included on the NLED price negotiation is the norm.
R&D tax incentives	Thailand offers a 200% deduction plus a further 100% tax deduction with capped amounts and an accelerated depreciation rate of 40% are available for eligible expenditures incurred on R&D activities carried out in Thailand. The R&D additional tax deduction is available only for payments to eligible Thai R&D service providers.
Factor 7: Rule of law	Ranked 76th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	88,7
Quality of academic publications, 2015	NA
Clinical trials per million population to date	36,05
Clinical trials for biologics per million population to date	2,95
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,91
Biotechnology triadic patenting, share of global total average 1999-2013	0,02%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	30,40%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	72,2
Biofuels production, % of global total, 2017	2,2%

TURKEY

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	1,215.8 (World Bank 2015)	
Life sciences graduates (PhD & Masters), per million population	22.4 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1% (OECD 2017)	
BERD spending as a % of total	49.5% (OECD 2017)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	6-yr RDP term of protection in place but based on EU product entry not domestic market entry. No PTE term in place. Achieved a score of 45.81% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	Localization drive continues and was strengthened over the last few years. The Turkish Medicines and Medical Devices Agency has drawn up plans to require drugs that face at least one local generic or therapeutic equivalent to localize production by 2018 or be excluded from reimbursement list. As a result, 45 drugs with at least a 50% market share and three local equivalents have been identified and delisted from reimbursement in February 2018. Similarly, the Turkish Government's 2016 Action Plan promised to introduce purchase guarantees for local "upper middle and high-tech products" (as done in the IT sector). The model was tested for pharmaceuticals in January 2016 with the announcement of a 7-year purchase commitment for a firm that launches a Hepatitis A vaccine manufacturing facility in Turkey. Since 2009 not only domestic companies but also foreign ones must include a GMP certificate from the MoH and produced by its inspectors with the registration dossier for all pharmaceutical products including those manufactured abroad. However, the MoH does not possess sufficient technical expertise and capacity (including adequate number of staff) and resources to carry out on-site checks in a timely manner, particularly for foreign manufacturing sites. The result is significant delays in market approval.	
Ag-biotech regulations	Turkey published its Biosafety Law in 2010. As of October 2018, only 36 (10 soybean and 26 corn) events have been approved for feed use (less than in the EU, which causes trade disruptions). No events are approved for food use or cultivation. Any GE presence in food products is prohibited. For feed, there is a 0.9% allowance for low level presence of approved events, but zero tolerance for unapproved GE traits The Biosafety Law contains severe liability, sanction, and penalty clauses that penalize noncompliance with large fines and five to twelve years in prison. The approval process is being update. Disincentives in the forms of official controls, approvals, liability, and prohibition on the cultivation of agricultural biotechnology also discourage R&D.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	Turkey has been working to improve technology transfer with local and regional partners. In conjunction with the European Union, the Turkish Government created the "Technology Transfer Accelerator Turkey" to assist in the commercialization of technologies developed at Turkish universities and research centers. In 2018 the Patent and Trademark Office set up a company called "Turkish IP Valuation Engineering and Consultancy Services Corporation" to facilitate IP commercialization. Impact so far in terms of outputs has been limited but Government action through TUBITAK and others is nevertheless positive.
Global Innovation Index 2018, University/Industry collaboration	3.5 (score, 0-7)	

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks (continued)		
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.5 (score, 0-1)	Recordal of IP licenses is not required but beneficial to enforce the licenses with third parties. IP right holder has to submit the duly executed license agreement. The new IP Code no longer categorizes extending the scope of a license agreement without the patentees consent as an infringing act
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	In recent years drug pricing has been one of the most problematic issues for innovators and generics alike. Within the public reference price system in place, prices are set for both innovative drugs and generics at 60% of the lowest price for the same product in a basket of five European countries. Yet, Turkey employs a fixed FX rate instead of market value to convert the value of euros into local currency. Each year the exchange rate should be determine to reflect 70% of the average exchange rate the preceding year, but is often lower than that. Turkey has further tightened its pricing policy by changing the way reference prices are calculated through the Communiqué on the Pricing of Medicinal Products for Human Use enacted September 2017. Also, in December 2017 the Turkish Social Security Institution has decided to limit adjustments to drug price increases in reference countries.	
R&D tax incentives	A number of generous R&D incentive programs and tax benefits are in place for both biotech and generally. There is a general 100-150% deduction for qualifying expenditure depending on the size of the company; smaller companies qualify for the larger deduction. There is also an 80-90% reduced rate of tax withholding for personnel involved in R&D activity. Special incentives are in place for domestic manufacturing of biopharmaceuticals.	
Factor 7: Rule of law	Ranked 109th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	309,9
Quality of academic publications, 2015	4,4
Clinical trials per million population to date	45,40
Clinical trials for biologics per million population to date	2,06
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,35
Biotechnology triadic patenting, share of global total average 1999-2013	0,02%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	25,10%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	65,2
Biofuels production, % of global total, 2017	Negligible

UAE

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	2406 (World Bank 2016)	
Life sciences graduates (PhD & Masters), per million population	NA	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1% (World Bank 2016)	
BERD spending as a % of total	NA	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	No RDP term of protection or PTE term in place. Achieved a score of 35.97% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	DRA generally viewed as highly capable with new fast-track approval initiative introduced in 2015, further improved in 2018 (reliance pathways with 30-day approval timeline).	
Ag-biotech regulations	No biotechnology regulatory framework in place (limited agricultural production/ cultivation in general). Some unenforced regulations requiring labeling in place.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.5 (score, 0-1)	Growing emphasis on technology transfer and public-private partnerships in R&D. Key part of both Vision 2021 and National Innovation Strategy. Fragmented and inconsistent licensing oversight - Free zones (over 30) have individual licensing authorities and can introduce own competition rules. Main universities (including Abu Dhabi University and UAE University) have in place tech transfer frameworks. The first biotechnology innovation incubator in the region was launched in Abu Dhabi University in 2012. Dubai Science Park is a free zone that provides a platform to Life Sciences, New Energy and Environment communities. Over 230 business partners out of 280 operate in the life sciences, including global industry players Pfizer, Amgen, Bristol-Myers Squibb, Maquet, Firmenich and IFF. Other examples include the Khalifa Center for Genetic Engineering & Biotechnology (created in 2014 from the United Arab Emirates University and the Ministry of Presidential Affairs) where scientists apply biotechnology and genetics to desert plants to make them better able to endure and prosper in dry, hot and salty conditions. And the Reproductive Biotechnology Centre in Dubai, an R&D center focusing on animal biotechnology. There is also the Masdar company, a strategic government initiative tasked with investing, incubating and advancing the establishment of a clean energy industry that includes the Masdar Institute of Science and Technology.
Global Innovation Index 2018, University/Industry collaboration	4.5 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	Licenses shall be recorded in the Register, in order to have effect against third parties. where a license of any IP right is signed outside the UAE, the document must be legalized at the UAE embassy in that country. It then must be legalized again and translated into Arabic on receipt in the UAE. Recording a license can take about eight months.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0.5 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	Price and profit controls in place. System of reference-based pricing in place. References include other GCC countries, wholesale and retail prices in country of origin etc. Tendency for UAE price to be determined based solely on cost.
R&D tax incentives	Not applicable. Corporation tax applied at the emirate level but only to oil and gas companies, tough a corporate tax scheme is being studied. Lack of profit tax, as well as withholding tax that would apply to payments such as royalties.
Factor 7: Rule of law	Ranked 32nd out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	135,7
Quality of academic publications, 2015	NA
Clinical trials per million population to date	20,96
Clinical trials for biologics per million population to date	0,64
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,32
Biotechnology triadic patenting, share of global total average 1999-2013	0,01%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	21,10%
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	69,1
Biofuels production, % of global total, 2017	Negligible

UK

INPUTS		
Factor 1: Human capital		
Number of researchers per million population	4429.6 (World Bank 2016)	
Life sciences graduates (PhD & Masters), per million population	233.8 (OECD 2016)	
Factor 2: Infrastructure for R&D		
R&D spending % of GDP	1.7% (OECD 2017)	
BERD spending as a % of total	51.8% (OECD 2016)	
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA	
Biotech R&D as a percentage of BERD	NA	
Factor 3: Intellectual property protection	10-yr RDP term of protection and 5-yr SPC term in place. Achieved a score of 93.9% on the IP Index life sciences indicators.	
Factor 4: The regulatory environment		
Biopharmaceutical regulations	The UK has a strong clinical and regulatory environment. For biopharmaceuticals the MHRA is responsible for the authorization and safety supervision of pharmaceuticals. The Agency works hand-in-hand with the EMA to ensure the proper dissemination of drugs approved at the EU-wide level. With regards to the UK leaving the EU and the EMA, there is a clear risk that this could lead to delays in approval and product launches with products needing to be re-registered.	
Ag-biotech regulations	While the UK embraces GM food products the current list of genetically modified seeds approved for planting by the EU are not suitable to the UK's growing environment, so there is limited commercial biotech crop cultivation. Also, Northern Ireland, Scotland, and Wales have opted out from GE maize production under the EU directive, but not England.	
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	The UK maintains a sophisticated and active technology transfer environment. Universities such as Oxford, Cambridge and Imperial College are active participants in transferring and commercializing research and technology. In terms of direct central government support for technology transfer Innovate UK maintains a web portal that allows members of industry, academia, potential funders and entrepreneurs to collaborate on ideas. In 2016 the Government issued a new Industrial Strategy. The strategy is aimed at better leveraging key assets of the UK and addressing remaining structural barriers to the UK's global competitiveness through promoting supportive conditions, including an additional GBP 2 billion invested per year. One challenge identified is to not only develop but also commercialize new technologies in UK (rather than selling them off to non-British firms). As part of this the government established a new Industrial Strategy Challenge Fund (ISCF) specifically targeting priority technologies – with biotech one of the top priorities. In the first announcement of funds, over GBP 1 billion is committed over 4 years focusing on 6 areas, which include healthcare and medicines.
Global Innovation Index 2018, University/Industry collaboration	5.4 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.75 (score, 0-1)	While the registration of licenses is not required by the Patent Act, it is advisable to do so as a way of notifying third parties and putting the licensee in a stronger position in potential infringement proceedings. No Government intervention in licensing terms between private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	

INPUTS (CONTINUED)	
Factor 6: Market and commercial incentives	
Biopharmaceutical pricing and reimbursement policies	The UK has a highly regulated pricing environment with the NHS negotiating prices with the pharmaceutical industry through the PPRS. Companies that do not participate in the voluntary PPRS are subject to the statutory scheme that imposes a list price cut of 15% on products. Discussions on reforming the PPRS have been ongoing with the Government tabling a Bill in Parliament in late 2016 increasing price regulations to also cover generic medicines. This was followed by the Competition and Markets Authority leveling a fine of a major manufacturer of over USD100 million for alleged excessive pricing. New Cancer Drugs Fund (launched in July 2016) has been fundamentally revamped with a fixed budget introduced and all decisions for reimbursement to be made by NICE.
R&D tax incentives	The UK offers R&D tax incentives to both small and large companies. SMEs can qualify for a super-deduction on qualifying R&D activities of 230% and SMEs that post a yearly loss can additionally qualify for up to 33.3% cash back on R&D related spending. A patent box regime offering a 10% rate of corporation tax to profits generated from patents is in place.
Factor 7: Rule of law	Ranked 12th out of 126 countries

OUTPUTS	
Scientific publications per million population, 2003-2016	1420,4
Quality of academic publications, 2015	13,6
Clinical trials per million population to date	249,46
Clinical trials for biologics per million population to date	20,77
Early phase (Phase I and II) clinical trials for biologics, per million population to date	10,27
Biotechnology triadic patenting, share of global total average 1999-2013	5,24%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	50,6%
National % share total number of patents from top 50 PCT applicants: universities, 2016	1%
Biotechnology crops, hectares under cultivation, % of total 2016	None
BCI Survey Ranking 2017	Mixed
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	94,4
Biofuels production, % of global total, 2017	0,7%

US

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	4313.4 (World Bank 2015)
Life sciences graduates (PhD & Masters), per million population	72.6 (OECD 2016)
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	2.8% (OECD 2017)
BERD spending as a % of total	63.6% (OECD 2017)
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	137.5(OECD 2016)
Biotech R&D as a percentage of BERD	12.3% (OECD 2016)
Factor 3: Intellectual property protection	12-yr RDP term of protection for biologics in place, 5-yr term for NCEs and 5-yr PTE term in place. Achieved a score of 95.78% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	
Biopharmaceutical regulations	The FDA sets and enforces rigorous standards. The FDA plays a leading role in efforts to harmonize regulatory standards through the International Conference on Harmonization. Moreover, the regulatory standards of the FDA are frequently emulated and recognized as a gold standard amongst clinicians, health economists and the academic community. In response to criticism of long approval times new expedited pathways have been introduced. Major new legislation in 2016 21st Century Cures Act which allows for: • Draft guidance on interchangeability of biosimilars released in Jan 2017 (final guidance yet to be released) • FDA final guidance on naming biologics and biosimilars issued in Jan 2017 allows for all biologic products to be distinguished from one another instead of generic naming: in addition to the INN it requires an FDA-designated suffix to distinguish product by product. • As a result of the (re)authorization of user fees for biosimilars (specifically under the Biosimilars User Fee Act) FDA also commits to faster timelines for originator biologics review (within 10 months); communication and guidance for biologics sponsors in advance of the review as well as during the review in order to anticipate needed changes and avoid delays in approval; and devoting greater resources for biologics review. • The Act also widens scope of permissible clinical trial data for approval of new biopharma products including observational studies, anecdotal data, and other informal types of data in additional to formal clinical trial results
Ag-biotech regulations	The Coordinated Framework for Regulation of Biotechnology is generally viewed as being one of the key building blocks and drivers of American biotech innovation. Since its announcement in 1986 the policy and subsequent sector-specific regulations are seen as having been instrumental in promoting the development of the American biotechnology industry and bringing a wide array of biotechnology products and technologies to consumers.

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	1 (score, 0-1)	One of the key drivers of American biotech innovation and commercialization has been the success of technology transfer in the US. The Patent and Trademark Law Amendments Act of 1984 and 1986 (commonly referred to as the Bayh-Dole Act) and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003 have all been instrumental in incentivizing technology transfer. These laws gave institutions that received federal support (such as American universities, small businesses and non-profits) control and the rights to any resulting intellectual property of their inventions or research.
Global Innovation Index 2018, University/Industry collaboration	5.7 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	1 (score, 0-1)	Registration of licenses with the USPTO is allowed but not required. No Government intervention in the licensing terms among private entities.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	1 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	The US has a relatively free market in the purchase and sale of biopharmaceutical products. There are no national price regulations or national reimbursement agencies. Instead, private health insurers and public payers (such as Medicare, the VHA and Medicaid) negotiate prices with manufacturers and only indirectly set reimbursement limits and influence prescribing and patient usage through the use of formularies. Drug formularies (which often include therapeutic interchange or so-called switching mechanisms) and differential cost sharing (such as tiered co-payments) are two of the more commonly used techniques to influence prescribing practices. Arguably, one of the strongest drivers of biopharmaceutical innovation in the US has been the existence of this relatively free market in the pricing of pharmaceuticals.	
R&D tax incentives	The US provides only limited R&D tax credits, both at the federal and state level. The federal Research and Experimentation Tax Credit allows companies to claim a tax credit of between 14-20% of qualifying amounts. In addition, 39 US states offer R&D tax credits at varying rates. Tax legislation passed December 2017 scaled back incentives to promote rare disease research (reducing the tax credit companies can claim on R&D costs from 50% to 25%).	
Factor 7: Rule of law	Ranked 20th out of 126 countries	

OUTPUTS	
Scientific publications per million population, 2003-2016	1235,4
Quality of academic publications, 2015	13,9
Clinical trials per million population to date	368,45
Clinical trials for biologics per million population to date	29,88
Early phase (Phase I and II) clinical trials for biologics, per million population to date	21,96
Biotechnology triadic patenting, share of global total average 1999-2013	41,83%
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	53,10%
National % share total number of patents from top 50 PCT applicants: universities, 2016	58%
Biotechnology crops, hectares under cultivation, % of total 2016	39,52%
BCI Survey Ranking 2017	Attractive
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	100
Biofuels production, % of global total, 2017	43,9%

VIETNAM

INPUTS	
Factor 1: Human capital	
Number of researchers per million population	672.1 (World Bank 2015)
Life sciences graduates (PhD & Masters), per million population	NA
Factor 2: Infrastructure for R&D	
R&D spending % of GDP	0.4% (World Bank 2015)
BERD spending as a % of total	NA
Total biotechnology R&D expenditure in the business sector, millions USD PPP, per million population	NA
Biotech R&D as a percentage of BERD	NA
Factor 3: Intellectual property protection	5-year RDP term de facto unavailable: request for data protection must be submitted within 12 months from the date a MA was first granted in any country in the world. No PTE; yet, in the EU-Vietnam FTA, expected to be signed in 2018, Vietnam committed to a 2-year patent term restoration system Achieved a score of 37.72% on the IP Index life sciences indicators.
Factor 4: The regulatory environment	
Biopharmaceutical regulations	Though improving, the regulatory environment remains weak (for instance, bioequivalence obligation applies to a limited part of generics, with a target to achieve 40% of them by 2020) and regulatory procedures are burdensome (e.g. long registration renewal procedure every 5 years; requirement for local clinical trials for product variations and phase III trials for vaccines); Positively, the new Pharma Law (Law 105/2016/QH13) introduces a new timeline for Marketing Authorization issuance, and removes some requirements for domestic clinical trials. However, language of the provision is vague and details are lacking. Furthermore, the current draft Circular on Clinical Trials still requires local clinical trials for product variations and phase III trials for vaccines. In 2017 the Prime Minister entrusted the MoH to work out a strategy on the development of a high-quality pharmaceutical industry with a vision toward 2030. Target to increase the share of locally procured pharmaceuticals to 80% of market volume and value by 2030.
Ag-biotech regulations	Vietnam has undertaken a number of initiatives that could hamper existing and future GE cultivation. These include delay of GE events and biotech crop approval, a proposal to ban glyphosate, and new conditions for the import, production, and trade of GE food and feed, whereby GE products must obtain a certificate satisfying conditions for food/feed use prior to importation, production, and trade in Vietnam.

INPUTS (CONTINUED)		
Factor 5: Technology transfer and commercialization frameworks		
Existence of technology transfer framework with clear and defined IP provisions (IP Index Indicator 26)	0.25 (score, 0-1)	A new Law on Technology Transfer from June 2017 aims to boost science and technology efforts, encourage the adoption of the latest advances from abroad, and prevent the import of outdated technologies. The law seeks to address barriers faced in the commercialization of scientific research and technological development. It encourages research institutions and organizations to collect market information, understand societal needs and engage in joint research activities with enterprises. It also promises to define ownership rights and the rights to use assets developed through scientific research. Finally, it makes registration of technology transfer contracts compulsory and restricts transfer of technology for treating products using biotechnologies, and technology for propagation and/or cultivation of new plants/animals which has not been tested; Under the law, policies covering the definition of ownership. Since the beginning of the 2000s, the government has also begun building National Key Laboratories within Vietnam Academy of Science and Technology (the country's main research institute with 2500 researchers employed) and other institutes, which seek to promote international research and bridge the gap from applied research to the commercialization of innovative products. They include the NKL on gene technology, NKL on plant cell technology and NKL on protein technology. A partnership between RMIT University and the Biotechnology Center of Ho Chi Minh City was concluded to contribute to the development of the ag-biotech industry in Vietnam. rights and the rights to use assets developed through scientific research, will be issued to support start-ups
Global Innovation Index 2018, University/Industry collaboration	3.5 (score, 0-7)	
Registration and disclosure requirements of licensing deals (IP Index Indicator 27)	0.25 (score, 0-1)	Registration of licenses makes them enforceable against third parties. A request for recordal of license agreement will be refused if there is a dispute over the IPR that are licensed. The 2017 Tech Transfer law also prospects adding (through secondary regulations) restrictions on the transfer into Vietnam of technologies which Vietnam has studied and used with the same level and efficiency as world technologies. Registration of a TT contract is mandatory for technology coming into Vietnam from a foreign country, or domestic tech transfer with the use of state funds.
Direct Government intervention in setting licensing terms (IP Index indicator 28)	0 (score, 0-1)	
Factor 6: Market and commercial incentives		
Biopharmaceutical pricing and reimbursement policies	Costly import regime inflates cost, insurance and freight prices, used for comparison with neighboring countries when fixing prices of imported products. Furthermore, final prices are calculated on the basis of prices declared by local distributors. Long reimbursement delays, around 5-6 years for newly approved drugs. The National Reimbursement List is only reviewed every 2 years. Government plans to establish by 2020 a central drug procurement unit for national procurement and price negotiation; and promote centralized procurement of drugs.	
R&D tax incentives	Biotech and R&D investment as well as other high-tech activities benefit from Corporate Income Tax (CIT) reduction, including a 4-year CIT exemption. The new Law on Technological Transfer grants special tax incentives for the import of R&D machinery, equipment, which have yet to be produced in the country.	
Factor 7: Rule of law	Ranked 81st out of 126 countries	

VIETNAM (CONTINUED)

OUTPUTS	
Scientific publications per million population, 2003-2016	12,6
Quality of academic publications, 2015	NA
Clinical trials per million population to date	4,31
Clinical trials for biologics per million population to date	0,62
Early phase (Phase I and II) clinical trials for biologics, per million population to date	0,27
Biotechnology triadic patenting, share of global total average 1999-2013	NA
Biopharmaceutical product launches, % available in country within 5 years of global product launch, 1983-2000	NA
National % share total number of patents from top 50 PCT applicants: universities, 2016	None
Biotechnology crops, hectares under cultivation, % of total 2016	0,01%
BCI Survey Ranking 2017	Challenging
Venture Capital & Private Equity Country Attractiveness Index, Economy Ranking, 2018, score out of 100	60,7
Biofuels production, % of global total, 2017	Negligible

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