MOEA

2020 Introduction to Biotechnology and Pharmaceutical Industries in Taiwan (R.O.C.)

Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO), MOEA

Photo by Marina Perez on Unsplash

Contents

02 Preface

04 Bravo Taiwan

08 Why Taiwan

12 Taiwan's Competitive Advantages

16 Overview of Taiwan's Biomedical Industry

20 One-Stop Service Window for Biomedical Industry

24 Contacts Worldwide for Taiwan's Biomedical Industry

Preface

The biomedical industry is an industry that focuses on research and development, and it achieves innovations and creates high additive values by integrating technologies of different fields. Along with innovations and development in biotechnology, the biomedical industry has become a crucial party promoting economic growth, maintaining human health, and ensuring environmental sustainability. Taiwan has been developing its biomedical industry since the 1980s, and has approved and implemented several policy programs aiming to promote the development of the biomedical industry, creating a favorable environment for the development of this industry.

Implemented in 2016, the Biomedical Industry Innovation Program has achieved satisfactory results under the joint effort of the industry and the government. Substantial growth has been observed in the turnover, investment amount, and the number of domestic and international licenses obtained for new medicine and medical devices. For example, in 2018, Taiwan became a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and had all its medical laws and regulations revised according to international standards. By the end of February 2019, six new drugs developed by Taiwanese companies have obtained international drug permit licenses, and 49 quality medical devices have acquired the FDA 510(K) premarket notification from US Food and Drug Administration, demonstrating the achievements of innovation in Taiwan's biomedical industry.

The 2018 turnover of Taiwan's biomedical industry was NT$514.8 billion (approximately US$17.07 billion), with a growth of approximately 5.6%. Civil investment in the biomedical industry reached NT$55.264 billion (approximately US$1.83 billion), which grew by 5% compared with 2017. In addition, as of June 2019, Taiwan has 123 listed and 61 emerging-stock biomedical companies. Specifically, biomedical companies that focus on research and development, have new medicines entering the stage clinical trial, or have unique products have grown considerably. By using multiple fund-raising channels in the capital market, these companies can raise the required research and development as well as operating funds.

The promotion and implementation of biotechnology industry policies aims to trigger innovation in the industry and increase its momentum for growth. Furthermore, such policies aid domestic companies in joining the global supply chain of biomedical products, thereby scaling up Taiwan's biotechnology industry. In addition, given the favorable research, development, and investment environment in Taiwan as well as the innovative capacity of vibrant industries, the policies also help international companies to invest in Taiwan or find business partners, thereby elevating Taiwan's international status in this industry and build Taiwan into an industrial stronghold of biomedical research and development in the Asia-Pacific region.

Richard Lee

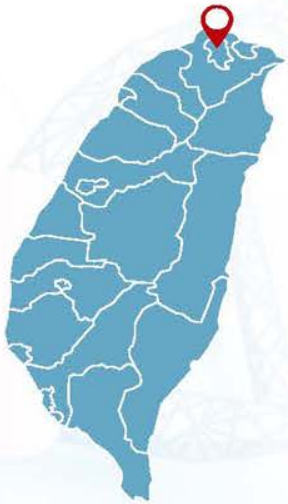
Director General
Industrial Development Bureau, MOEA
October, 2019

Bravo Taiwan

General Environment

Taiwan is located at the southernmost point of Northeast Asia in the center of the East Asian island arc and on the western edge of the Pacific Ocean, with Japan and the Ryukyu Islands to its north and the Philippines to its south. Taiwan is not only a crucial Asia-Pacific trade and logistics hub but also a major strategic base. Its 36,000 km^2 area encompasses diverse natural resources and rich cultures.

Capital: Taipei
Land Area: 36,000 km^2
Population: 23.50 million
Primary Ethnic Groups: Han Chinese, Aboriginal Groups, and New Immigrants
Languages: Mandarin, Taiwanese, Hokkien, Hakka, and Indigenous Languages
Religions/Belief Systems: Buddhism, Taoism, Folk Beliefs, Christianity, and Islam



Pleasant Climate

Taiwan remains warm throughout the year, with greater temperature variations in spring and winter than in summer or fall. The average annual temperature is 22 °C, with lows typically hovering at approximately 12 – 17 °C. The south is generally warmer than the north, with average January temperatures of approximately 16 °C in Taipei and 20 °C in Kaohsiung.

Asia-Pacific Hub

Taiwan serves as an Asia-Pacific transportation hub connecting Northeast and Southeast Asia. Its first-rate international airports enable convenient travel averaging only 2.55 hours from Taipei to five major western Pacific cities (Tokyo, Seoul, Shanghai, Hong Kong, and Manila), and world-class Kaohsiung Port facilitates goods shipment averaging only 53 hours to five major regional ports (Manila, Singapore, Hong Kong, Shanghai, and Tokyo). Taiwan not only forms a crucial link for Europe, America, and Japan with emerging Asia-Pacific markets but also is a preferred location for multinationals establishing their regional headquarters.

Stable Political System

Taiwan is currently a member of several international economic organizations, including the World Trade Organization, the Asia-Pacific Economic Cooperation group, and the Asian Development Bank, and engages in regular trade and exchanges with over 140 countries worldwide. As the global economy becomes more liberal and develops more rapidly, Taiwan is continually adjusting its industrial strategies, easing regulations, removing investment restrictions, and reinforcing intellectual property measures in line with international trends.

Major Economic Indicators, Taiwan 2018

GDP
US$589.997 billion

Economic Growth
2.6%

Foreign Exchange Reserves
US$ 467.23 billion (end of 2019.07)

Export Value
US$335.91 billion

Import Value
US$286.33 billion

Unemployment
3.73% (end of 2019.06)

Labor Participation Rate
59.12 (end of 2019.06)

*Sources: National Statistics, R.O.C. (Taiwan)

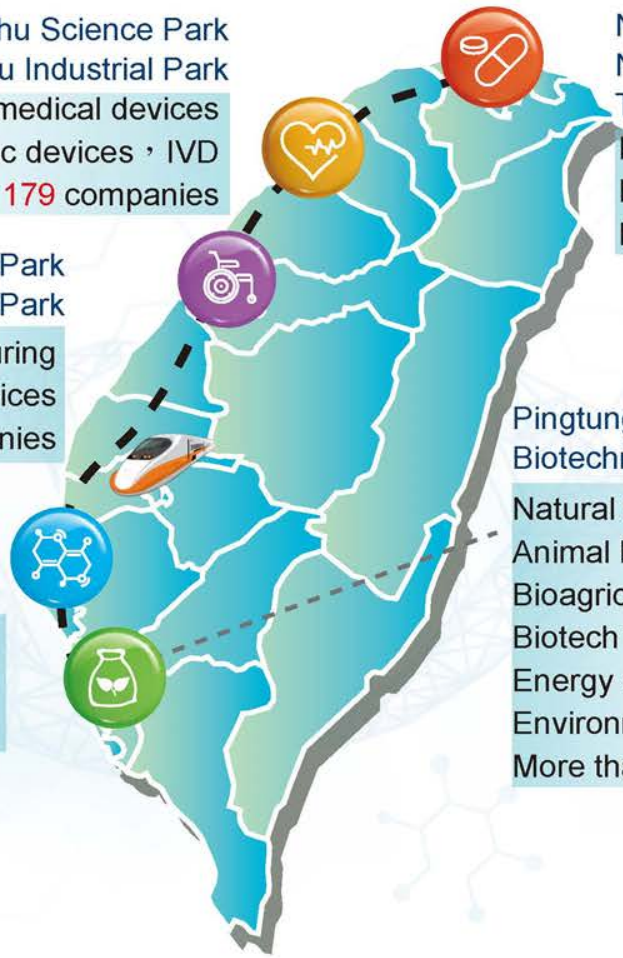
Why Taiwan

Comprehensive Bio-industrial Clusters

Hsinchu Science Park
Hsinchu Industrial Park
Vaccine, medical devices
in vitro diagnostic devices，IVD
More than 179 companies

Central Taiwan Science Park
Central Region Industrial Park
Drug manufacturing
Medical devices
More than 569 companies

Southern Taiwan Science Park
Southern Region Industrial Park
Generic drugs, implants
Instruments for minimally invasive surgery
More than 553 companies



National Biotechnology Research Park
Northern Region Industrial Park
Taipei Neihu Technology Park
New Drug Discovery
Medical device development
More than 753 companies

Pingtung Agricultural
Biotechnology Park
Natural health and beauty
Animal biotechnology
Bioagricultural materials
Biotech testing
Energy conservation
Environmental control and agricultural facilities
More than 104 companies

台灣高鐵
TAIWAN HIGH SPEED RAIL
90 min
One-day living circle

*Sources:
The Ministry of Science and Technology Industrial Development Bureau, Ministry of Economic Affairs The Council of Agriculture, Executive Yuan Taipei City Government

8 Investment Advantages

Asia-Pacific Medical Hub

Taiwan serves as an Asia-Pacific transportation hub connecting Northeast and Southeast Asia.

Reliable Legal Environment

Taiwan has a mature and well-established legal system. Additionally, regulations for commercialization are timely adjusted in line with changing international norms, and foreign investors enjoy substantial protection under the Statute for Investment by Foreign Nationals.

Comprehensive Bio-industrial Clusters

Taiwan has built up biotech and medical industry clusters based on local characteristics and geographical environment.

Excellent Labor Force

Taiwan's excellent labor force is retained by its universal education system, which produces more than 300,000 new graduates each year at the college level or above.

Sound Infrastructure

Taiwan has a dense, comprehensive transportation network and relatively inexpensive water, electricity ,and telecommunications utilities that approach 100% penetration.

Diverse Culture of Innovation

Taiwan boasts a thriving R&D sector. Innovative elements bring worldwide popularity to its high-tech consumer electronic products, chain store services, bicycles, pearl milk tea and Chinese-language music.

Well-Protected Intellectual Properties

Regarding protection for intellectual properties, Taiwan adheres to international treaties and norms. The relevant policies and laws are open and transparent in Taiwan.

Friendly towards Fundraising and Financing

Abundant capital, stable exchange rates, and relatively low interest rates and capital costs make Taiwan a friendly environment for fundraising and financing.

Taiwan's Competitive Advantages

WORLD ECONOMIC FORUM

In the Global Competitiveness Report 2018 issued by the World Economic Forum (WEF), Taiwan ranks 13th among 140 economies and 4th in the Asia-Pacific. the report as a “super innovator” as one of four economies, alongside Germany, Switzerland and the U.S., to receive more than 80 in innovation capability.

THE ADECCO GROUP

The Global Talent Competitiveness Index 2019：Taipei finished 15th in the world and 1st in Asia, and the number of talents retained is the highest in the world.

THE WORLD BANK

In the World Bank's "Doing Business 2019" report, Taiwan finished 13th out of 190 economies for ease of doing business.

IMD
REAL LEARNING. REAL IMPACT

In the World Competitiveness Ranking 2019 report by the International Institute for Management Development(IMD), Taiwan‘s competitiveness ranks 16th out of 63 countries and 4th in the Asia-Pacific.

BOAO FORUM FOR ASIA

In the Boao Forum for Asia (BFA) “Asia Asian Competitiveness Annual Report 2019 ” , Taiwan finished 2nd out of 37 economies.

Taiwan's Advantages

- Abundant biotech personnel familiar with the European, US, and Asian markets.
- Active capital markets and convenient fundraising channels.
- One-Stop Service Window for the biomedical industry (Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO), MOEA).
- Drug review regulations conforming to international standards and pharmaceutical processes in accordance with internationally accepted PIC/S GMP specifications.
- Taiwan Clinical Trial Consortium (TCTC), working to promote Taiwan as an Asia-Pacific regional leader in new drug and clinical trials and facilitate development and commercialization of international and domestic biomedical products.

FDA

Taiwan Clinical Trial Consortium

* Act for the Recruitment and Employment of Foreign Professionals Act https://foreigntalentact.ndc.gov.tw/en

Target Discovery	Product Dev.	Pre-Clinical	Clinical			Market
Molecular Targets	Target Screening	New Compound, Med. Devices (Reagents)	Hit Confirmation	ADME Non-Clinical Dev.	IND/IDE Application	Clinical Evaluation	NDA/PMA Application	Launch & Post-Market Surveillance

320,000 People / Year

Taiwan Clinical Trial Consortium

PIC/S GMP Taiwan FDA

- Breast Cancer
- Cardiovascular Disease
- Dementia
- Gastrointestinal Disease & Helicobacter
- Infectious Disease
- Liver Diseases
- Lung Cancer
- Mental Disorders
- Oncology Phase I
- Pediatric Infectious Disease
- Renal Disease
- Stroke
- UGI Cancer

· 13 Disease-specific clinical trial consortiums
· 281 Highly motivated and devoting investigators

694 Industry-sponsored trials
· International Sponsors 496
· Domestic Sponsors 128

265 Investigator initiated trials

272 Investigators as global chairman or advisory board member

1135 Publications

89.8% The achievement rate of site initiation

222,299 Subjects recruited

* Sources: Taiwan Clinical Trial Consortium, 2019

Overview of Taiwan's Biomedical Industry

The Taiwanese government has designated biomedicine as one of the“5+2 innovative industries” for priority development. The Biomedical Industry Innovation Program aims to make Taiwan an Asia-Pacific biomedical R&D hub, focusing on “local, global, and future links” and comprising four action plans: building a comprehensive ecosystem, integrating innovation clusters,connecting global market resources, and promoting specialized key industries.

Biomedical Industry Innovation Program

- Building a comprehensive ecosystem
- Integrating innovation clusters
- Connecting to global markets
- Promoting specialized key industries

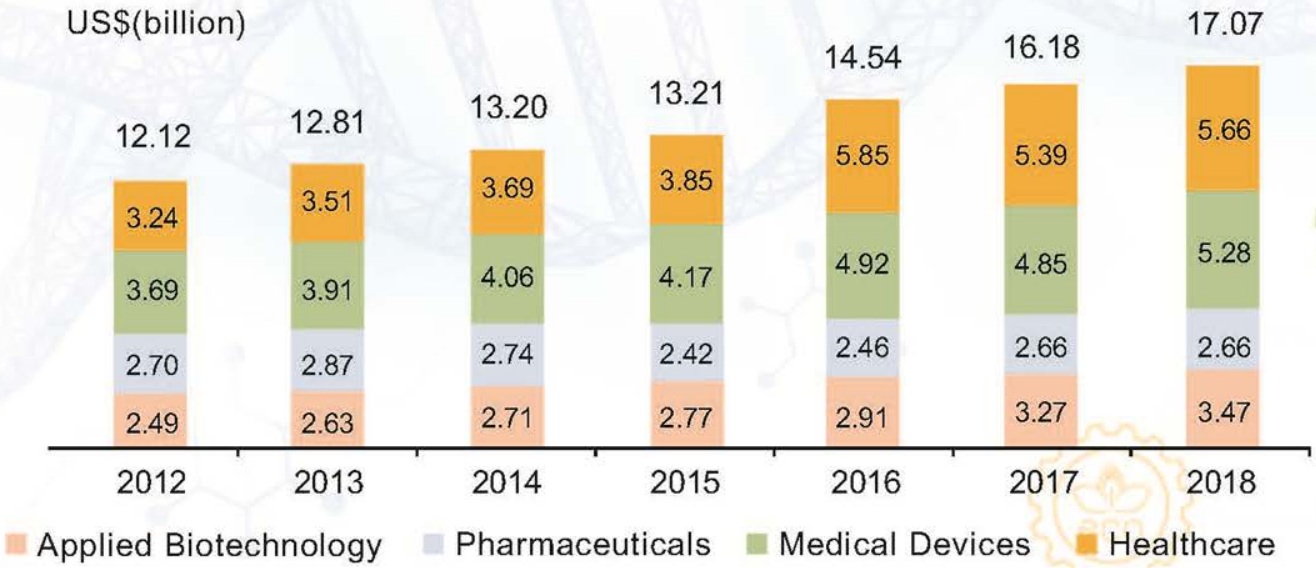
Taiwan’s biomedical industry comprises three major sectors: applied biotechnology, pharmaceuticals, medical devices , and healthcare services.

Biomedical Industry

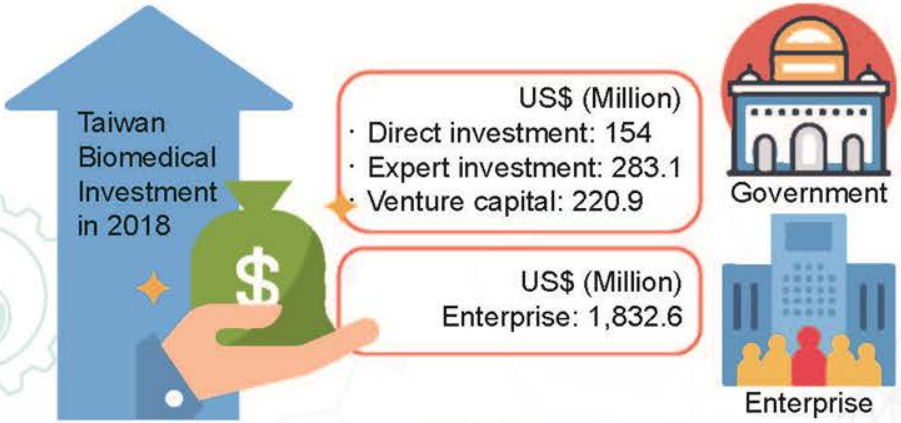
- **Applied Biotechnology** — Agriculture, Food, Environment Contract Services, Specialty Chemicals
- **Pharmaceuticals** — Small Molecule Drugs, Biologics, Active Pharmaceutical Ingredients, Traditional Chinese Medicine
- **Medical Device** — *In vitro* Diagnostics, Assistance and Compensatory, Surgery and Treatment, Diagnosis and Monitoring, Disease Prevention and Health Promotion, and other Miscellaneous Devices
- **Healthcare** — Healthcare Services, healthcare promotion, healthily services

In 2018, revenue in Taiwan's biomedical industries amounted to US$17.07 billion, representing a growth of approximately 5.6% over that in 2017 (US$16.18 billion).

Healthcare represent the largest subsector in Taiwan's biomedical industries, with the revenue of US$ 5.66 billion in 2018, or 33.16% of the total revenue in these industries. And medical devices represent subsector Taiwan's biomedical industries, with the revenue of US$5.28 billion in 2018, or 30.93% of the total revenue in these industries.



* Source: Biotechnology Industry in Taiwan 2019. IDB. MOEA



The public offering market represents a platform for the government, companies, and investors to raise funds and invest directly. Taiwan's negotiable securities market is divided into over-the-counter and exchange markets according to review conditions. Companies interested in becoming listed or nonpublic microenterprises intending to engage in innovative and creative undertakings can raise funds through the emerging stock market or the Go Incubation Board for Startup and Acceleration Firms (GISA) stock market by underwriting firms familiar with the relevant operations and regulations.

As of June 2019, Taiwan had 123 listed biotech and medical care companies, with a combined value of US$23.28 billion. In addition, 61 and 22 companies have registered on the emerging and GISA stock markets, respectively. Through diverse capital market fundraising channels for operating and R&D funds, the value of Taiwan's public capital market continues to increase.

One-Stop Service Window for Biomedical Industry

經濟部生技醫藥產業發展推動小組
Biotechnology and Pharmaceutical Industries Promotion Office, MOEA

Whatever you are seeking in the biomedical industry, the BPIPO's One-Stop Service Window is here to help.

The Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) is the single contact window for Taiwan's biomedical industry. It is an one-stop service window designed to assist companies in the biomedical industries worldwide. The assistances provided by BPIPO include: financial support, investment promotion, stock listing, personnel training and recruitment, R&D collaboration, technology transfer, commercialization, marketing, promotion activities, strategic alliances, and others.

Over the past few years, BPIPO has helped Taiwan's biomedical industry to obtain investments of more than US$1,500 million per year. BPIPO has also helped set up more than three innovative companies per year. The One-Stop Service Window has helped more than 100 companies per year.

Responding to private sector's consultation needs, the One-Stop Service Window for the biomedical industry provides a convenient, comprehensive, and interactive platform connecting the professional resources and service capacities of various ministries through webpages, email, and social media. This platform employs project management methods and provides 24-hour support. By compiling information and providing customized follow-up, the BPIPO assists the biomedical industry in overcoming investment and operational obstacles. Multilingual website interfaces are gradually being added to expand services for international vendors, who are thus able to obtain information on the status of Taiwan's biotechnology industry and related investment incentives and engage in investment and business cooperation.

We provide the following services:

- Consultation and referral services such as assistance for regulation and inspection units, technology transfer and commercialization, R&D and practical application, cooperation and investment promotion, and market information.
- Consultation on development policies, incentives, and applications.
- Assisting biotech and medical care companies in investing, fundraising, and conducting investment briefings.
- Information pertaining to land acquisition and the setting up.

One-Stop Service Window for Biomedical Industry Biotechnology and Pharmaceutical Industries Promotion (BPIPO)

https://www.biopharm.org.tw

Email:services@biopharm.org.tw

TEL:(886-2) 2655-8135

FAX:(886-2) 2655-8134

Contacts Worldwide for Taiwan's Biomedical Industry

Industrial Development Bureau, MOEA

Formulating industrial development policies, strategies, and measures; promoting programs related to industrial upgrading, development and management of industrial zones; formulating fiscal and financial measures for industrial development, industrial pollution control, industrial safety counseling and factory management, general industrial administration.

(886-2) 2754-1255
www.moeaidb.gov.tw
service@moeaidb.gov.tw

Biotechnology & Pharmaceutical Industries Promotion Office, MOEA

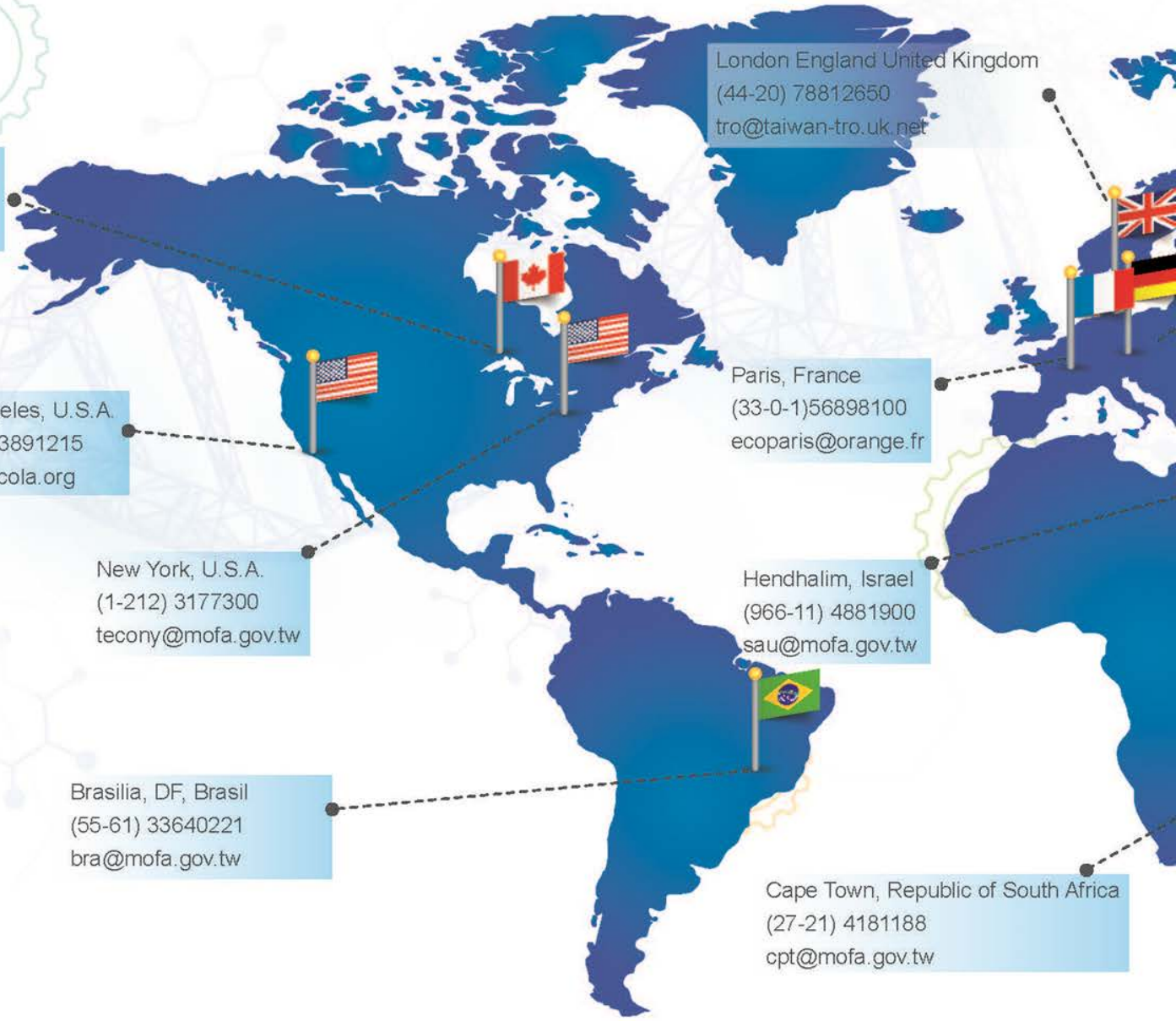
Acting as the single contact window for domestic and international biomedical-related industries; acting as One-Stop Service Window, promoting industrial investment and integration; assisting biotech, pharmaceutical, medical device industry development and upgrade.

(886-2) 2655-8135
www.biopharm.org.tw
services@biopharm.org.tw

InvesTaiwan Service Center, MOEA

The InvesTaiwan Service Center (ITSC) offers a single window for investment services, and uses a "project-oriented, dedicated case manager with specific responsibilities, and customized start-to-finish service" approach to assist investing firms.

(886-2) 2311-2031
https://investtaiwan.nat.gov.tw/showIndInfo?guid=2&lang=eng


London England United Kingdom
(44-20) 78812650
tro@taiwan-tro.uk.net
Ottawa, Ontario, Canada
(1-613) 2315080
can@mofa.gov.tw
Paris, France
(33-0-1)56898100
ecoparis@orange.fr
Los Angeles, U.S.A.
(1-213) 3891215
info@tecola.org
New York, U.S.A.
(1-212) 3177300
tecony@mofa.gov.tw
Hendhalim, Israel
(966-11) 4881900
sau@mofa.gov.tw
Brasilia, DF, Brasil
(55-61) 33640221
bra@mofa.gov.tw
Cape Town, Republic of South Africa
(27-21) 4181188
cpt@mofa.gov.tw

Seoul, Korea
(82-2) 3992780
kor@mofa.gov.tw

Berlin, Germany
(49-30) 203610
deu@mofa.gov.tw

Bangkok, Thailand
(66-2) 6700200
tha@mofa.gov.tw

Tokyo, Japan
(81-3) 32807811
vipass@mofa.gov.tw

Singapore
(65) 65000100
sgp@mofa.gov.tw

Jakarta,Indonesia
(62-21) 5153939
econidn@mofa.gov.tw

New Delhi, India
(91-11) 46077777
ind@mofa.gov.tw

Canberra, Australia
(61-2) 61202000
aus@mofa.gov.tw

Riyadh, kingdom of Saudi Arabia
(966-11) 4881900
sau@mofa.gov.tw

Wellington, New Zealand
(64-4) 4736474
tecowlg@taipei.org.nz

Bravo!

Biotechnology Taiwan

Photo by Tourism and Travel Department, New Taipei City Government

2020 Introduction to Biotechnology and Pharmaceutical Industries in Taiwan (R.O.C.)

Publisher: Industrial Development Bureau, Ministry of Economic Affairs
Address: No. 41-3, Sec. 3, Xinyi Road, Da'an District, Taipei City 106, Taiwan
https://www.moeaidb.gov.tw
Tel: (886-2) 2754-1255
Fax: (886-2) 2706-1933
Editor: Biotechnology & Pharmaceutical Industries Promotion Office, Ministry of Economic Affairs
Address: Room A, 17F, No. 3, Park Street, Nankang District, Taipei City 11503, Taiwan
https://www.biopharm.org.tw
Tel:(886-2) 2655-8135
Fax:(886-2) 2655-8134
Publication Date: Oct. 2019
Revision: First Edition
Price: NT$100 (COST)

Sales Center:
Wunan Cultural Plaza Bookstores
Address: No. 600, Junfu 7th Road, Beitun District, Taichung City 406, Taiwan (R.O.C.) Tel:(886-4) 2437-8010
https://www.wunanbooks.com.tw

Government Publications Bookstore
Address: 1F, No. 209, Songjiang Road, Zhongshan District, Taipei City 104, Taiwan (R.O.C.) Tel: (886-2) 2518-0207
https://www.govbooks.com.tw

The electronic file can be downloaded from https://www.biopharm.org.tw

ISBN:978-986-5442-01-9
GPN:1010801445
The Industrial Development Bureau, Ministry of Economic Affairs reserves all rights. Those who wish to use this book, in its entirety or in portions, must seek the consent or written authorization from the Industrial Development Bureau, Ministry of Economic Affairs.
Contact Information:(886-2) 2754-1255 # 3916 Library

2020 Introduction to Biotechnology and Pharmaceutical Industries in Taiwan (R.O.C.)

Publisher：Industrial Development Bureau, MOEA
Address：No. 41-3, Sec. 3, Xinyi Road, Da'an District, Taipei City 10657, Taiwan (R.O.C.)
Tel：(886-2) 2754-1255
Fax：(886-2) 2706-1933
https://www.moeaidb.gov.tw
Publication Date：Oct. 2019
Price：NT$100 (COST)
ISBN：978-986-5442-01-9
GPN： 1010801445

ISBN:978-986-5442-01-9
9 789865 442019