

出國報告（出國類別：參加國際會議）

**參加 APEC 生命科學創新論壇
(Life Sciences Innovation Forum)**

服務機關：經濟部 技術處

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派赴國家：日本

出國期間：2010/09/16-21

報告日期：2010/11/19

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壹、摘要

職鄭建新奉派於 99/09/16-20 前往日本仙台參加 2010 亞洲經濟合作會議(APEC)第八屆生命科學創新論壇(Life Sciences Innovation Forum VIII)，並應主辦單位邀請代表我國發表專題演講，講題為：**How Can Economies Enable New Growth?-A Case Study by Chinese Taipei**。本次會議主旨為"Building Economic Growth and Enhancing Health and Welfare through Health Innovation"(議程參附件一，簡報參附件二)。會前(9/17 早上)並前往東北大學(Tohoku University)，參訪 United Centers for Advanced Research and Translational Medicine (簡稱 ART)及其主任，Professor Toshio Miyata (官田敏男教授)。Miyata 教授曾於今年 7 月 18 日來台參加工研院主辦之"International Forum on Advances in Diabetes Complications"，因此安排參訪該中心以洽商合作機會之可行性(參附件四)。9/17 下午參加 LSIF Steering Committee Meeting，與我國代表醫藥品查驗中心(CDE)陳恆德執行長及衛生署曾琇婷博士等共同與會，討論以 APEC 為平台進行各經濟體在藥品與醫材審查法規協和化之各項議題。

貳、出差目的

- 一、參加 APEC LSIF VIII 第八屆生命科學創新論壇並發表專題演講
- 二、參訪東北大學洽談合作事宜
- 三、參加 LSIF Steering Committee Meeting

參、出差過程

- 一、參加 APEC LSIF VIII 第八屆生命科學創新論壇並發表專題演講

本次會議係 2010 APEC Senior Officials' Meeting III (SOM3)系列會議之一，其主要目的為 Building Economic Growth and Enhancing Health and Welfare through Health Innovation。全部議程為二天(9/18-19)，分為 11 個 Sessions，職被安排在第二天(9/19)早上 Session 7：Case Studies—How Can Economies Enable New Growth?中發表我國在該議題之專題報告，獲得大會主席泰國自然資源與環境部長 H.E. Minister Suwit Khunkitti 及議題主席輝瑞藥廠主管全球公共事務與政策副總裁 Dr. Marjory Searing (VP, Worldwide Public Affairs and Policy, Pfizer)的肯定，我國提出之研究報告與建議且獲大會共同主席，Dr. Peter Sheehan 採納，列為 LSIF 向今年 11 月舉行的部長與領袖會議的建議事項之一，期許 APEC 各經濟體能比照 Chinese Taipei 模式與範例，積極使用 LSIF 設計之"Enablers of Investment Checklist"進行各經濟體在生命科技領域的投資政策與環境評估工具。

專題演講重點摘錄如下：

1. 這份研究報告是跨部會合作的成果，結合衛生署、教育部、國科會、經濟部及台經院、科資中心以三個月時間協力完成。
2. 忠實依照"Enablers of Investment Checklist"進行我國在生命科學領域政府的政

策法規、智財保護、市場自由度、人力供需、投資環境、醫療健保、科技研發等方面之評估與建議。

3. 在計畫執行過程中，遇到不符國情、定義不明或窒礙難行的命題，則反應給 LSIF 總部進行調整或請求說明。
4. Enablers of Investment Checklist 共分為六大部分：(1) Increasing Human Capital；(2) Effective and Adequate Intellectual Property Rights (IPR) Systems; (3) Open and Competitive Markets and Free Trade; (4) Support for Research and Development; (5) Efficient and International Harmonized Regulatory Systems and (6) A Holistic and Transparent Approach to Health Care Policy，合計 95 項命題。完整書面報告已由衛生署委託醫藥品查驗中心(CDE)提交 LSIF，演講內容參考附件二之簡報。

本次會議經過二天聽取報告與討論後，由大會主席 H.E. Minister Suwit Khunkitti 根據日本擬訂之三項主題：1. Health Innovation and New Economic Growth Paths；2. Regional Economic Integration and Openness；3. Improving Human and Economic Security 作成大會結論和建議(參附件三)。其主要結論包括：

1. 各經濟體共識到提高在健康和生命科學創新的開支應被認為是強化經濟發展和社會福祉的投資而非僅是花費，因有了健康的國民和員工，才會有強盛繁榮的國家和具競爭力的企業。
2. LSIF 認為預防措施—尤其是保護健康者的健康是一應優先發展的創新領域。
3. 生命科學與生物科技創新系統應加速改革，使得全球價值鏈更能環環相扣，發揮最大效益。
4. 應善用先進的資訊科技(IT)進行健康醫療照護體系的效率提升，促使電子病歷更能廣泛被使用。
5. 簡化醫藥品查驗登記及法規制度，使得創新且安全有效的藥品與醫材能以更快的速度進入市場，造福患者，創造商機。

二、參訪東北大學洽談合作事宜

9/17 早上拜訪日本東北大學(Tohoku University)，United Centers for Advanced Research and Translational Medicine (簡稱 ART)及其主任，Professor Toshio Miyata (官田敏男教授)洽談合作事宜，官田教授是知名的腎臟醫學權威，現任國際腎臟醫學會理事，因其所研發的腎病新藥，在日本不易進行臨床試驗(病人數不夠多)，而台灣因洗腎患者眾多，反而累積了許多寶貴的臨床經驗與案例，這也促使他前來台灣與台灣腎臟科醫師合作的主因，官田教授為人極其熱情，很希望與台灣建立更緊密的藥品及生物標記(Biomarkers)合作開發關係，並獲其提供在診治腎臟疾病方面的研究成果及商品化構想(參附件四)。

三、參加 LSIF Steering Committee Meeting

9/17 下午參加 LSIF Steering Committee Meeting，與我國代表醫藥品查驗中心(CDE) 陳恆德執行長及衛生署曾琇婷博士等共同與會，討論以 APEC 為平台進行各經濟體在藥品與醫材審查法規協和化之各項議題。尤其是 APEC 經濟體之藥政主管單位擬在 GHTF(Global Harmonization Task Force)的架構下，推動於 2020 年達成 life-saving 醫療器材審查法規的協和化(參附件五)，這方面的發展是很值得期待與參與。

肆、心得與建議

- (1) APEC LSIF 會議每年定期舉辦三次，由當年 APEC 主辦國(2011 年為美國)負責議程籌劃，我國每年均由衛生署主政組團參加，經濟部工業局偶而派員隨團與會。今年因探討各經濟體在生命科學領域之政策法規與科技研發對經濟發展的影響，遂由職扛下重擔，負責協調各部會運用 LSIF 提供之"Enablers of Investment Checklist"，檢視我國在生物科技領域之投資環境，因評估客觀公正(不會只報喜，不報憂)，加上與中國大陸剛簽訂 ECFA 生效(99.09.12)，故藉此利多極力宣傳我國值得投資的各項優點，獲得 Session Chair, Dr. Marjory Searing (VP, Worldwide Public Affairs and Policy, Pfizer)的讚揚與肯定，當場期許各經濟體比照我國模式與範例，進行"Enablers of Investment Checklist"的自我評估。會後大會主席泰國自然資源與環境部長 H.E. Minister Suwit Khunkitti 也親自向職祝賀，欣慰我國為 LSIF 力推多年的政策檢視工具樹立美好標竿，值得各經濟體效法學習，他也希望能儘快來台參訪。
- (2) 建議未來本處及法人單位可積極參與 LSIF 相關之各項會議與活動，因其提供一交流平台，使產官學研均可在其上獲取第一手之研究資料並學習國際經合組織之運作模式。且許多與會者都是生物科技領域之重量級人物，可當面請教獲益或討論觀點，在其他場合不易有如此平易之交流平台。
- (3) 本份演講報告係職與先進技術推進辦公室同仁(廖湘儀、黃麗萍等)，結合其他部會(如衛生署劉麗玲組長、曾琇婷博士，國科會羅於陵博士等)及智庫夥伴們(如 CDE 陳恆德執行長、林治華博士、台經院林欣吾所長等)一起完成，得以獲得與會者廣泛好評，是團隊同心協力的成果，深感若無大家的貢獻，單靠個人是絕對無法達成任務的。
- (4) 在我國簽訂 ECFA 之後，可感受到我國市場行情節節高升，也成為亞洲國家可敬的對手或期望合作的夥伴，台灣應善用難得的契機趁勢崛起，多多參與像 APEC 這類的國際場合，爭取在國際舞台上發光發熱。

伍、附錄

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JAPAN 2010

APEC Life Sciences Innovation Forum VIII

*Building Economic Growth and Enhancing Health and Welfare
through Health Innovation*

**September 18-19, 2010
Sendai, Japan**

The Westin Sendai
Room A



Day Zero – September 17	
5:00 – 6:00	LSIF Board Meeting (closed) Location: The Westin Sendai, Vista Room
6:00 – 9:00	LSIF Board and Speakers Reception & Dinner Venue: Sendai Kokusai Hotel, departing from The Westin Sendai

Day One – September 18	
9:00 – 9:30	LSIF VIII Opening Session *Please be seated by 8:45*
	<p>Welcome Remarks</p> <ul style="list-style-type: none"> • Mr. Hidehiko Nishiyama, APEC 2010 SOM Chair and Director-General for Trade International Trade Policy, Ministry of Economy, Trade and Industry (METI), Japan <p>Vision for LSIF VIII</p> <ul style="list-style-type: none"> ▪ H.E. Suwit Khunkitti, LSIF Chair; Minister of Natural Resources and the Environment, Thailand <p>Building on LSIF VII 2009</p> <ul style="list-style-type: none"> ▪ Ms. Barbara Norton, LSIF Planning Group Chair; Deputy Assistant US Trade Representative, Office of Market Access and Industrial Competitiveness, Office of the US Trade Representative, United States
9:30 – 9:50	Setting the Scene: A View of Health Challenges and Opportunities in the Asia-Pacific Region
	<p>To set the scene for LSIF VIII, Mr. Hasegawa will give his view on the most immediate health challenges and opportunities in the Asia-Pacific region and on what is driving reform across the region.</p> <ul style="list-style-type: none"> ▪ Introduction by Mr. Charles Butcher, Director, Public Policy - Asia Pacific, Merck ▪ Mr. Yasuchika Hasegawa, President & Chief Executive Officer, Takeda Pharmaceutical Company Limited Japan and President, Japan Pharmaceutical Manufacturers Association
9:50 – 10:45	Session 1: Measuring the Economic Consequences of Health Innovation
	<p>How does life sciences innovation policy impact the economy? How does it influence individuals and the distribution of benefits across a society? How do life science policies impact economies' budgets? How do economies take this into account in determining both life sciences policies and budgetary priorities? How can economies</p>



	<p>enhance coordination between health, economic development, and budget officials? This session will explore these themes as they are presented in their research. This work is the continuation of their 2008 ground-breaking study on returns to investment in health innovation. Their presentation will be followed by a panel discussion.</p> <ul style="list-style-type: none"> ▪ Dr. Peter Sheehan, LSIF Academic Co-Chair, Center for Strategic Economic Studies, Victoria University, Australia ▪ Dr. Zheng Xiaoying, Director, Institute of Population Research, Peking University, People's Republic of China ▪ Comments by Dr. Tasuku Honjo, Senior member of the Council on Science and Technology Policy, Cabinet Office, Japan
10:45 – 11:00	COFFEE BREAK
11:00 – 11:45	Session 2: What Type of Growth? Health Innovation, Life Sciences and New Growth Strategies
	<p>Many economies are emphasizing growth while paying particular attention to the type of growth. In November 2009 APEC Leaders stated " We will put in place next year a comprehensive long-term growth strategy that supports more balanced growth within and across economies, achieves greater inclusiveness in our societies...and which seeks to raise our growth potential through innovation and a knowledge-based economy." How can health innovation generally, and life sciences in particular, play a role in this strategy?</p> <p>Moderator: Mr. Charles Butcher, Director, Public Policy - Asia Pacific, Merck</p> <ul style="list-style-type: none"> ▪ Mr. A. Sinclair Dunlop, CEO, Rock Spring Partners ▪ Dr. Douglas Crawford, Associate Director, The California Institute for Quantitative Biosciences, United States
11:45 – 12:15	Special Progress Report: APEC LSIF Harmonization Center (AHC)
	<p>The Director of the APEC LSIF Harmonization Center (AHC) will provide a progress update and discuss prospects for future work. The AHC was launched in Seoul, Korea in June 2009.</p> <ul style="list-style-type: none"> ▪ Dr. Seung Hee Kim, Director, APEC Harmonization Center (AHC)
LUNCH 12:30 – 2:30	Keynote: Life Science Innovation Policy in Japan Venue: Hotel Monterey Sendai *12:30 time indicates departure time from The Westin Sendai
	<ul style="list-style-type: none"> ▪ Dr. Tasuku Honjo, Senior member of the Council on Science and Technology Policy, Cabinet Office, Japan ▪ Comments by Mr. Chris Coburn, Executive Director, Cleveland Clinic Innovations, The Cleveland Clinic, United States



2:30 – 3:15	Session 3: Framing the Discussion: Building an Engine for Growth
	<p>The life sciences sector has the potential to contribute to growth and productivity in a variety of ways—understanding and harnessing that potential is the continuous challenge faced by economies. There are three focus areas where innovations have the potential to make the most changes – Health IT, biologics, and health and the environment. This session will frame the discussion for the “In Focus” sessions which will further explore developments in the three emerging life sciences areas and assess how economies can leverage innovation in these sectors to drive economic growth and productivity.</p> <p>Moderator: H.E. Hernán Garrido-Lecca Montañez, Former Minister of Health of Peru, Instituto de Gobierno de la Universidad San Martín de Porres, Peru</p> <ul style="list-style-type: none">▪ Dr. Tatsumi Yamazaki, Executive Vice President and Member of the Board, Chugai Pharmaceutical Co., Ltd▪ Mr. Chris Coburn, Executive Director, Cleveland Clinic Innovations, The Cleveland Clinic, United States▪ Mr. Neil de Crescenzo, Senior Vice President and General Manager, Oracle Health Sciences
3:15 – 4:00	Session 4: In Focus: Driving Growth through Health IT
	<p>Economies have found that supporting innovation and expanding the use of Health IT is facilitating and enhancing growth and productivity. However, there are significant gaps and barriers to successful deployment of Health IT throughout the region. This session will discuss priorities in the development of mechanisms, frameworks and guidance on the role of innovation and communication technologies in health systems.</p> <p>Moderator: Dr. Akihiko Tamura, Councilor for APEC, Ministry of Economy, Trade & Industry, Japan</p> <ul style="list-style-type: none">▪ Professor MyoungHo Lee, President, Korea e-Health Association, Republic of Korea▪ Mr. Hisatoyo Kato, Chairman, Japan Industries Association of Radiological Systems (JIRA)▪ Mr. Kenei Shie, Committee Member, International Division, Japan Industries Association of Radiological Systems (JIRA)▪ Dr. Noriyuki Moriyama, Doctor, National Cancer Center of Japan
4:00 – 4:45	Session 5: In Focus: The Emergence of Biologics
	<p>Medical biologics are emerging as the fastest growing sector of life science innovation – 65% of innovative pharmaceutical market growth is attributed to this area. Discussants will examine ways in which economies can position themselves to capture this growth market. In this session, key issues confronting the biologics sector such as regulatory competence and risk conditions will be discussed. An</p>



	<p>economy representative will also provide and overview of the regulatory perspective.</p> <p>Moderator: Dr. Marjory Searing, Vice President, Worldwide Public Affairs and Policy, Pfizer</p> <ul style="list-style-type: none">▪ Mr. Kunihiko Suzuki, Senior Executive Officer, Corporate Strategy & Planning, MEDINET Co., Ltd.▪ Mr. Yoshiaki Tsukamoto, Executive Director, Japan Bioindustry Association▪ Dr. Pornchai Matangkasombut, President, Mahidol University, Thailand
4:45 – 5:30	Session 6: In Focus: Assessing and Addressing the Health Impacts of Environmental Change
	<p>Economies have revealed that there are significant gaps in knowledge on the health impacts of environmental change. This session will assess and address issues and new developments concerning the environment's impact on health outcomes in the APEC region. Discussants will also review progress made in examining the regional health and economic impacts of emerging and re-emerging infectious diseases as well as acute and chronic climate-change related dislocation.</p> <p>Moderator: Dr. Leslie Mancuso, President and CEO, Jhpiego</p> <ul style="list-style-type: none">▪ Dr. Tjandra Yoga Aditama, Director General, Disease Control and Environmental Health, Indonesia▪ Professor Ian Wronski, Pro-Vice-Chancellor, Faculty of Medicine, Health and Molecular Sciences, James Cook University, Australia▪ Video message by Dr. Peter J. Hotez, President, Sabin Vaccine Institute, United States
5:30 – 5:45	Day 1 Concluding Remarks
	<p>Dr. Peter Sheehan, LSIF Academic Co-Chair, Center for Strategic Economic Studies, Victoria University, Australia</p>
DINNER 6:45 – 9:30	"Caring for the Economy – Re-thinking the Value of Health Care" Venue: Hotel Monterey Sendai *6:30 time indicates departure time from The Westin Sendai
	<ul style="list-style-type: none">▪ Introduction by Mr. William Bishop, Director of Government & Public Affairs - Japan, Becton, Dickinson and Company▪ Keynote address by Dr. Otmar Kloiber, Secretary General, World Medical Association▪ Closing by Mr. Seiji Miyazawa, Director of International Affairs, Japan Pharmaceutical Manufacturers Association (JPMA)



Day 2 – September 19	
9:00 – 9:10	Day 2 Opening Session *Please be seated by 8:45*
	<p>Summary of Day One</p> <ul style="list-style-type: none"> ▪ H.E. Suwit Khunkitti, LSIF Chair; Minister of Natural Resources and the Environment, Thailand
9:10 – 9:30	Morning Keynote: The Contributions of the Medical Device Industry to Health Care Innovation and Economic Development
	<p>As we approach the era of the aging society, we face important issues such as whether we can provide advanced, high quality, efficient healthcare in a way that is safe, prompt and low cost to a large number of people transcending borders. This is indispensable in order to ensure a stable quality of life as well as contribute to the economic development of each region.</p> <ul style="list-style-type: none"> ▪ Introduction by Dr. Peter Sheehan, LSIF Academic Co-Chair, Center for Strategic Economic Studies, Victoria University, Australia ▪ Mr. Kazuo Ogino, Chairman, Japan Federation of Medical Devices Associations (JFMDA), Chairman & CEO, Nihon Kohden Corp.
9:30 – 10:15	Session 7: Case Studies: How Can Economies Enable New Growth?
	<p>In 2008 LSIF created the “Enablers of Investment Checklist.” The stated goal of the Checklist is for economies to use it as a tool “to assess and improve the environment for investment in the innovative life sciences sector...thus boosting both health and economic outcomes.” This session will provide a brief overview of the Checklist, followed by presentations from APEC economies that have completed the Checklist in 2010: Canada and Chinese Taipei. Each economy will briefly present its results and lessons learned, to be followed by a group discussion.</p> <p>Moderator: Dr. Marjory Searing, Vice President, Worldwide Public Affairs and Policy, Pfizer</p> <ul style="list-style-type: none"> ▪ Dr. Chien-Hsin Daniel Cheng, Advisor, Science & Technology, Department of Industrial Technology, Ministry of Economic Affairs, Chinese Taipei ▪ Mr. Mike Ward, Chair of the LSIF Regulatory Harmonization Steering Committee, International Policy Division, Health Canada
10:15 – 10:30	COFFEE BREAK
10:30 – 12:00	Session 8: Health Financing Mechanisms and Options: Feedback Session from The Economist’s Conference on Healthcare in Asia (March 2010, Singapore)
	<p>Individual companies fit into a broader picture driven by economy-specific policies. How do different models for health financing compare across APEC? What</p>



	<p>mechanisms do these policies have in common? How are they different? A clear understanding among policymakers of the different models being used is a prerequisite for successful policy in the future. This session will explore these themes in the context of the output of The Economist's Conference on Healthcare in Asia: Priorities for Reform (March 2010, Singapore).</p> <p>Moderator: Mr. Charles Goddard, Editorial Director, Asia, Economist Intelligence Unit</p> <ul style="list-style-type: none"> ▪ Dr. Haichao Lei, Director, Department of Policy and Regulation, Ministry of Health, People's Republic of China ▪ Mr. Chen Changxiang, Director, Medical and Pharmaceutical Industry Development Research Centre (MPIDRC), People's Republic of China ▪ Dr. Akira Morita, Professor, Former Dean, Graduate School of Public Policy, The University of Tokyo, Japan ▪ Dr. Hasbullah Thabrany, Professor, Institution Center for Health Economics and Policy, Universitas Indonesia, Indonesia
12:00 – 12:35	Session 9: What is the Role of the Individual Company?
	<p>While economies are concerned with macro-economic issues such as new growth strategies, in most economies a major source for growth will be individual companies. How does the average company view health? LSIF research points towards a need for economies to view and account for not only the costs of health innovation, but also the benefits. Should companies do the same?</p> <p>Moderator: Mr. Sean Sullivan, President and CEO, Institute for Health and Productivity Management, United States</p> <ul style="list-style-type: none"> ▪ Dr. Fikry Isaac, Executive Director and Chief Medical Officer, Global Health Services, Johnson & Johnson
LUNCH 12:35 – 1:30	WORKING LUNCH Venue: The Westin Sendai, Room A
	Japanese lunch boxes will be brought in as participants continue discussions.
1:30 – 2:15	Session 10: APEC Cooperation in Medical Life Sciences
	<p>The leaders of the LSIF regulatory agenda provide an update on progress and prospects for future work.</p> <ul style="list-style-type: none"> ▪ <i>Regulatory Harmonization</i> – LSIF has established itself as the leading voice in the region on regulatory harmonization and related trade issues. This meeting, to be led by the Chair of the LSIF Regulatory Steering Committee, will examine the latest priority issues, including the ongoing development of the APEC LSIF Harmonization Center and the next set of associated LSIF projects. <ul style="list-style-type: none"> ○ Moderated by Mr. Mike Ward, Chair of the LSIF Regulatory Harmonization Steering Committee, International Policy Division,



	<p>Health Canada</p> <ul style="list-style-type: none"> ○ Mr. Shinobu Uzu, International Planning Director (Pharmaceutical Affairs) Minister's Secretariat, Ministry of Health, Labour and Welfare, Japan ○ Mr. Hiroshi Ishikawa, Chairman of International Division, Japan Industries Association of Radiological Systems (JIRA) <p>▪ <i>Quality of Medicines:</i></p> <ul style="list-style-type: none"> ○ Mr. Jeffrey Gren, Director, Office of Health and Consumer Goods, International Trade Administration, Department of Commerce, United States
<p>2:15 – 3:00</p>	<p>Session 11: Building a Long-term Vision for Regional Cooperation</p>
	<p>LSIF has seen remarkable progress in the short period of time in the area of regulatory harmonization. There also has been work in the Health Working Group on pandemic preparedness. Is it possible to identify areas of potential policy overlap among economies? If overlap exists, how can it be leveraged to enhance cooperation and improve health outcomes across the region? What lessons have been learned in the region regarding health financing mechanisms and options? What are the prospects for enhanced research collaboration?</p> <p>Moderator: Professor Ian Wronski, Pro-Vice-Chancellor, Faculty of Medicine, Health and Molecular Sciences, James Cook University, Australia</p> <ul style="list-style-type: none"> ▪ Dr. Daehee Kang, Professor of Preventive Medicine, Molecular and Genetic Epidemiology Laboratory (MGEL), Seoul National University College of Medicine, Republic of Korea ▪ Dr. Michael Towns, WW Vice President - Medical Affairs, Becton Dickinson Diagnostic Systems ▪ Mr. Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic
<p>3:15 – 5:45</p>	<p>Closing Session: Developing Draft Conclusions and Recommendations</p>
	<p>Presentation: Draft Conclusions and Recommendations to APEC Ministers and Leaders</p> <ul style="list-style-type: none"> ○ Dr. Peter Sheehan, LSIF Academic Co-Chair, Center for Strategic Economic Studies, Victoria University, Australia ○ H.E. Hernán Garrido-Lecca Montañez, Former Minister of Health of Peru, Instituto de Gobierno de la Universidad San Martín de Porres, Peru ○ Professor Ian Wronski, Pro-Vice-Chancellor, Faculty of Medicine, Health and Molecular Sciences, James Cook University, Australia ○ Dr. Marjory Searing, Vice President, Worldwide Public Affairs and Policy, Pfizer ○ Dr. Leslie Mancuso, President and CEO, Jhpiego ○ Mr. Charles Goddard, Editorial Director, Asia, Economist Intelligence Unit



- **Mr. Sean Sullivan**, President and CEO, Institute for Health and Productivity Management, United States
- **Dr. Akihiko Tamura**, Councilor for APEC, Ministry of Economy, Trade & Industry, Japan

Group Discussion: Draft Conclusions and Recommendations to APEC Ministers and Leaders

Dr. Peter Sheehan, LSIF Co-Chair, Australia

Closing Remarks

H.E. Suwit Khunkitti, LSIF Chair, Thailand

How Can Economies Enable New Growth?

- A Case Study by Chinese Taipei

Chien-Hsin Daniel Cheng
Ministry of Economic Affairs
September 19, 2010



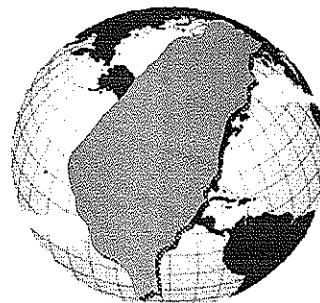
Acknowledgement

A Combined Effort by Chinese Taipei!

Department of
Health
(DOH)

Ministry of
Economic Affairs
(MOEA)

National
Science Council
(NSC)



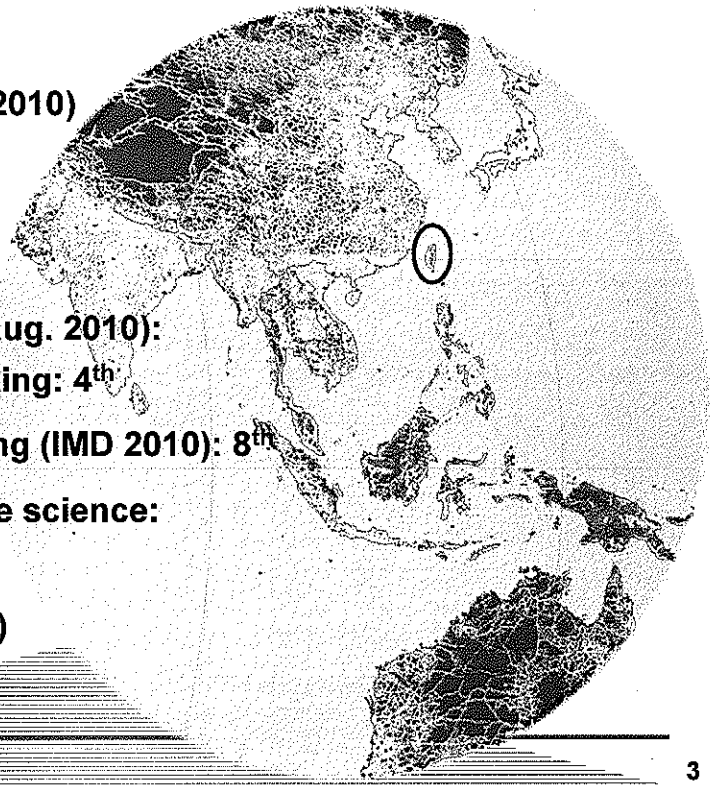
Ministry of
Education
(MOE)

Taiwan Institute of
Economic
Research (TIER)

Science &
Technology Policy &
Information Center
(STPI)
- National Applied
Research Lab

A Snapshot of Chinese Taipei

- Area: 35,980 sq km
- Population: 23,145,020 (Aug. 2010)
- GDP: 378.1 billion USD (2009)
 - Per capita: 16,390 USD (2009)
 - Global ranking: 22th (2009)
- Foreign exchange reserves (Aug. 2010):
372.1 Billion USD. Global ranking: 4th
- Global competitiveness ranking (IMD 2010): 8th
- Gross R&D expenditure for life science:
0.3% of GDP (2009)
- Life Expectancy at birth (2009)
 - Males: 75.88 years
 - Females: 82.46 years



Chinese Taipei - Centrally Located in East Asia



Enablers of Investment

1 Increasing human capital

2 Effective and adequate intellectual property rights (IPR) systems

3 Open and competitive markets and free trade

4 Support for research and development

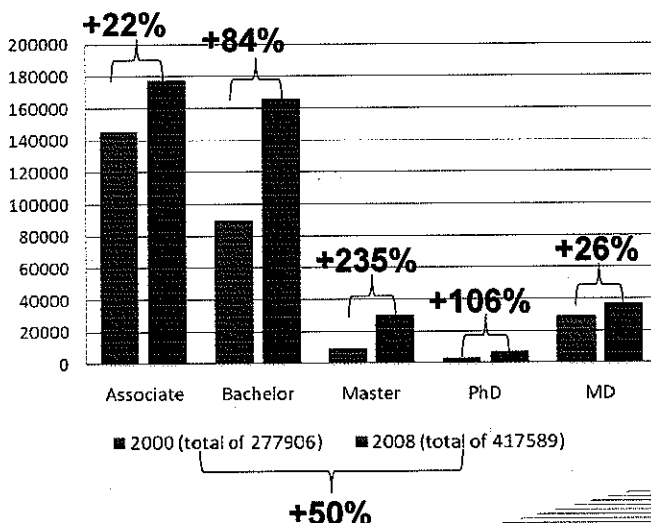
5 Efficient and internationally harmonized regulatory systems

6 A holistic and transparent approach to health care policy

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1. Increasing Human Capital

Total stock of HRST in the field of life science: (by degree)



● Government Policies

- Biotech Industry Promotion Program (1995)
- Science and Technology Professional Training Program (2003)
- Biotechnology and New Drug Promotion Program (2007)

• Relevant policies:

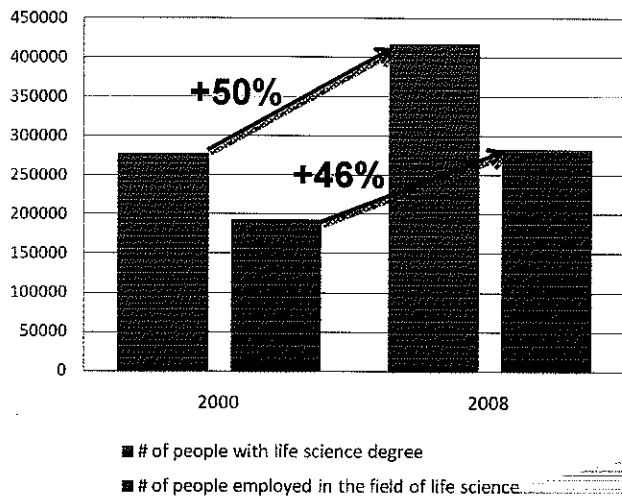
- Enhance education for professional and managerial expertise
- Enhance post graduate training
- Recruit experts from abroad

● Personnel Training:

- Number of graduate level programs
 - Graduate: 583 (13.6%)
 - Undergraduate: 577 (9.5%)
- Number of certified teachers
 - Graduate: 982 (10.1%)
 - Undergraduate: 6676 (16.5%)

1. Increasing Human Capital

Total stock of HRST in the field of life science: (by education vs. job position)



● R&D Organizations

- 10 non-profit organizations
- 8 major professional societies

● Findings and Lessons Learned:

- Large proportion of human capital is correlated to **basic training & healthcare services**
- Highly in need of **upper management** professionals with R&D and international experience
- Even though the number of graduates in life science increases, whether or not these graduates can be fully employed in the relevant job market remains a critical issue

Source: Monthly statistic report on human resource by STPI

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2. Effective and Adequate Intellectual Property Rights (IPR) Systems

● Re-examine the Chinese Taipei IPR environment according to the enablers of investment

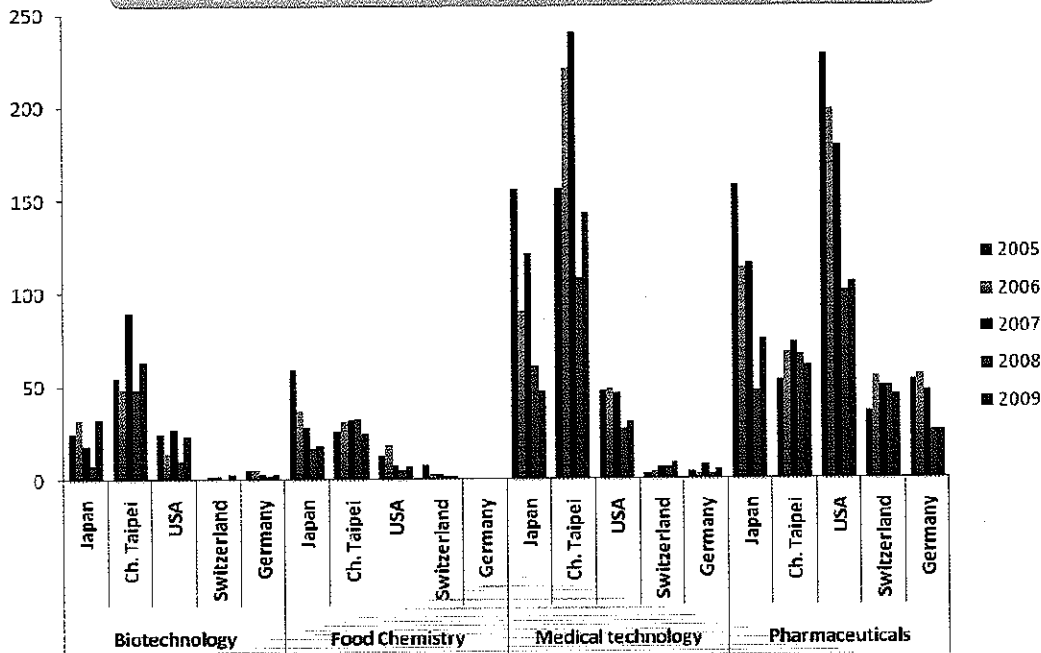
- Policies:** National Science and Technology Development Plan 2009
- Laws:** Patent Act (Amended and promulgated on 2003); Patent Attorney Act (Promulgated on 2007)... etc
- Provisions**
- Enforcements:** By the newly established IP court
- Process:** Transparent and friendly to innovation

● Findings and Lessons Learned:

- Coupled with a complete patent protection system, Chinese Taipei has plenty of patent capability which prompts many developed countries to apply for local patents
 - Patent term provided for innovative medicines and medical devices: **20 years**
 - Time required for patent acquisition: **Average 46 months***
- Though not part of the Patent Cooperation Treaty (PCT), Chinese Taipei has a comprehensive IPR system. On Sept. 9, 2010, the Executive Yuan approved the IPR Promotion Program to invest US\$380M in the next 6 years (2010~15). One of its action items will be to reduce the patent processing time to under 2 years

2. Effective and Adequate Intellectual Property Rights (IPR) Systems

Number of patents granted in Chinese Taipei:



Note: The four technology fields of Life Science is categorized according to "IPC AND TECHNOLOGY CONCORDANCE TABLE" published by WIPO. Source: TIPO, 2010 August

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2. Effective and Adequate Intellectual Property Rights (IPR) Systems

● Intellectual Property Court - established 2008

• Goals:

- To determine disputes concerning IPR validity
- To speed up the adjudication process
- To provide effective rights-related remedies

- 8 professional judges from the Taipei High Administrative Court
- 14 technical examiners from the IPO

● The combined functions of civil, criminal, and administrative appeal litigation is a special feature of the IP Court and a first in Asia

● Current Progress:

- In Jan 2009, the US Trade Representative removed Chinese Taipei from its Special 301 Watch List in recognition of the progress made in improving IP protection and enforcement
- July 2008-July 2009: Total of **254** cases on IP closed
- **An example:** In 2009, the court settled a drug litigation for US company E.L. against a top domestic generic drug company



3. Open and Competitive Market and Free Trades

- **Rules for capital flow aligned with the principles of an open and competitive market**
 - Comply with international standard under the WTO framework
- **Trading rights compliant with principles of an open and competitive market**
 - The **Economic Cooperation Framework Agreement (ECFA)** that aims to reduce tariffs and commercial barriers between China and Chinese Taipei (Effective on Sept.12, 2010)
- **Decreasing tariffs and NTBs to regional trade in life science products**
 - Zero tax for life science product imports with approval certification from DOH
- **Levels of combined public and private investment in life science**
 - Private: 325M USD (2008)
 - Government: 828M USD (2008)

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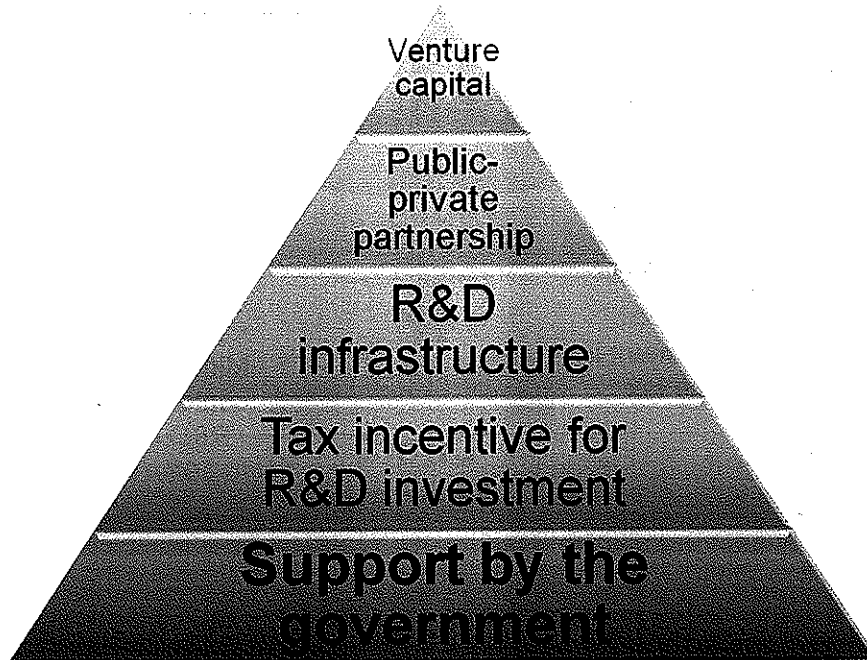
3. Open and Competitive Market and Free Trades

- **Adequate physical infrastructure to ensure appropriate delivery of therapies**
 - **Case study:** In response to the 2009 global H1N1 pandemic, Adimmune Corporation manufactured the H1N1 flu vaccine promptly for domestic use
- **Healthcare system is responsive to the introduction of new medical therapies**
 - **Case study:** A targeted therapy for lung cancer, Iressa, has recently been approved for complete reimbursement by the National Health Insurance
- **Concerns**
 - Under the regulation of the Bureau of National Health Insurance (BNHI), the prices of brand name drugs may be discounted, a policy that could be considered unattractive by brand name drug pharmaceuticals

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4. Support for Research and Development

Enablers of an ideal R&D environment:



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4. Support for Research and Development

The Perspectives in Chinese Taipei Biotech Takeoff: The Diamond Action Plan

SIC is a private operation investing in both government and private sector

Software —

- Integrated national biotech projects
- Provide services related to legal, IP, technical, & business operational issues
- Bridge industry & academia

Hardware —

- Protein manufacturing facility (MOEA or private sector)
- Animal Research Laboratory (NSC)

- Process (Efficiency and transparency)
- Industry development
- Regulatory harmonization

Software —

- Organizational culture reform
- Incentive mechanism

Hardware —

- Establish foundation for pre-clinical trial studies (toxicology & PK)
- Establish Rapid Prototyping Service Center

Industrialization

R&D Centers

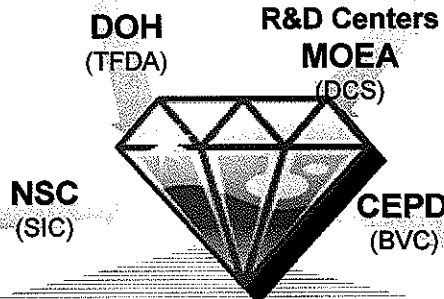
MOEA (DCS)

- Staged investment to diversify risk (Government : Private = 40:60)

- Accountable private VC investment team

- Establish management consulting company

- Initial capital: \$2-300M USD
- Targeted capital: \$1.9B USD



SIC: Supra-Incubation Center ; BVC: Biotech Venture Capitals

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