

議題壹：行動生活產業科技發展策略

I 觀感

1. 針對未來行動生活型態之技術發展策略

- 1.1 本計劃目標具企圖心兼具可行性。可運用台灣特有的優勢，如行動電話的高普及率和無線區域網路產品的製造優勢等。但仍需要克服台灣產業在軟體強調不足與技術研發不足的弱點。
- 1.2 本計劃規畫之研究方向稍嫌狹隘，忽略了隱私/安全與人機介面等重點。
- 1.3 雖然本計劃提出的開放測試平台值得鼓勵，但應盡速規劃和執行。在基礎建設方面，並未強調系統架構的重要性，也未討論在技術與文化層面跨領域整合的困難度。
- 1.4 本計劃欠缺有說服力，及得以發揮台灣特有優勢的應用。

2. iB3G 技術、服務與應用之研發策略

- 2.1 我們全力支持此高風險、高報酬的旗艦型計劃。相信本計劃將對台灣資訊與通信技術的發展具顯著影響：
 - 2.1.1 打破 OEM/ODM 為主的思維，協助台灣的製造業向技術產業鏈上游（例如 IC 設計、軟體產業等）提昇。
 - 2.1.2 促進手機業者與服務和內容提供者之間的跨業合作。
- 2.2 智慧財產權為本計劃重要產出之一，應落實保護。

3. 行動生活應用與服務之推廣策略

- 3.1 本計劃清楚傳達行動生活的現況與發展策略，如類似將台北建造為全球第一的無線寬頻城市的做法是相當好的。我們支持繼續積極建

設寬頻無線之基礎建設，以成為服務與應用的發展平台及技術發展的環境。

- 3.2 雖然在 2003 年已完成九項無線寬頻區域網路的展示，2004 年還有其他計劃陸續進行，但在應用面的普及方面以及數位內容業者的參與意願方面，都略顯不足。這是一個警訊，因為發展策略性服務業的支援環境是 2003 年的主題。必須找出發展的障礙及解決方案。

4. 行動生活製造業與服務業的合作策略

目前製造業與服務業的合作尚嫌不足。

5. 建置整合的行動生活法規環境

- 5.1 一般社會大眾對交通部電信總局政策制定的考量和原因並不清楚，例如民眾不知何種與行動位置相關的資訊可被業者使用。
- 5.2 有關提昇低使用率頻道的提案是合理的。
- 5.3 有關設置法律單位負責管轄數位內容授權平台的建置和運作的提案，可行性不高，需要仔細審核。對於平台之運作方式，或是否應全權交由民間機構管理，仍需再研究。
- 5.4 行動生活之隱私權保護是重大問題，需要全盤檢核。若只討論行動位置的隱私權，似嫌狹隘。

6. 推廣共同標準與建立國際認證/測試環境

- 6.1 在參與國際標準制定活動時，應對本地產業的發展有幫助，且有清楚的目標與議題。
- 6.2 由政府參與標準制定仍待商確。這與一些其他地區政府的做法並不相同。
- 6.3 CCRA 對產業重要性，特別是台灣產業，似乎不高。

II 建議

1. 針對未來行動生活型態之技術發展策略

- 1.1 政府應評估在這些策略領域的人力資源供需情形，並提出短中長期計劃，以解決人力資源問題。
- 1.2 本計劃應具系統觀，亦即定義全面性的架構，清楚說明主要的軟體組件應如何交互作用等。
- 1.3 本計劃應擴展其技術面向到安全/隱私、人機介面、資訊管理等。在每一方面，都應提供發展時程規劃。
- 1.4 本計劃應提出重要的應用，例如健保或營運等，以發揮台灣的優勢。
- 1.5 應分析執行本計劃之風險，並提出減低風險之機制。
- 1.6 本計劃應提出績效評量指標 (KPI)以追蹤進度。

2. iB3G 技術、服務與應用之研發策略

- 2.1 全力提供本計劃所需要的資源，以利積極進行。
- 2.2 政府應建立機制推動此類創新但具高風險的計劃。
- 2.3 iB3G 之研發應涵蓋安全/隱私與兼具聲音與視覺的人機介面等部分。
- 2.4 為保護智慧財產和提昇市場接受度，鼓勵本計劃參與相關之標準制定組織，如 IEEE 802.xx。
- 2.5 前項建議中所提的人力資源、重要應用、政府角色、風險管理以及績效評量指標等，也適用於本項建議。

3. 行動生活應用與服務之推廣策略

- 3.1 設立一具競爭力和支援性的環境，對於促進創新應用與服務極為重要。政府應該在高人口密度的都會區，建設無線寬頻基礎，並列為國家首要建設之一。
- 3.2 我們贊成行動生活應用與服務發展計劃，但需要提供績效評量指標來評核其執行績效。
- 3.3 建立行動生活產業的價值鏈分析。應找出阻礙無線生活/應用生態體系發展的因素(例如，對內容提供者的誘因，消費者接受度等)，並積極與產業配合，以消除這些阻礙。建議參考日韓的經驗。
- 3.4 研究以跨產業的方法積極推動數位內容產業的發展。
- 3.5 推動研究消費者對行動生活應用與服務偏好或使用行為，了解需求面的問題，發展重要應用項目。
- 3.6 新行動台灣計劃可當成實現行動生活願景與目標的載具。

4. 行動生活製造業與服務業的合作策略

- 4.1 促成製造業者與服務業者合作成立開發聯盟。
- 4.2 促成與行動生活相關之科技與傳統產業的合作。
- 4.3 鼓勵產業成立行動通訊與應用等方面之智慧財產保護聯盟。

5. 建置整合的行動生活法律環境

- 5.1 鼓勵交通部電信總局提昇其法令制定的程序的透明化。
- 5.2 開放低利用率之頻道給其它的應用及服務。
- 5.3 交通部電信總局應重新思考其所建議的數位內容授權平台的運作機制，例如是否由民間機構主導，或先設置一小型、概念性的試用平台，供特定政府所有的資訊試用。

- 5.4 在個人行動位置的隱私保護相關之規定方面，應採負面表列方式，因此方式適用於現階段對於隱私權、便利性與其他考量之間的權衡，尚未明朗之際。

6. 推廣共同標準與建立國際認證/測試環境

- 6.1 應重點支持具明確產業目標及企圖的標準制定活動。
- 6.2 所提出參與 CCRA 的提議應暫緩，待適合時機再議。（即使美國的 CC 測試實驗室，每年僅執行少許案例，成效不彰。）
- 6.3 本計畫所提認證與測試平台應在取得本地產業之確認、支持和指引之後，方可進行。決議之後，應以公平競爭方式，選取最合適的組織或實驗室，來開發與經營這些測試設施。

議題貳：安全產業的發展策略與展望

I. 觀感

這個議題有三個主要題綱：

1. 安全產業與科技的發展策略
2. 策略性安全產業的推動措施
3. 強化安全產業的發展環境

安全與資通安全是兩個不同的產業，在這個前提下，安全產業（安全設備等）是個明確且成熟的產業，而且可能不會有太多新的發展機會。現在有一個新的趨勢與複雜的系統安全有關（例如可設定及更改的系統），但這方面仍剛起步。

在另一方面，資訊、通信及網路安全產業，是個新興的產業，對於台灣的經濟有很大的影響，不但有潛力可以發展成新公司帶動經濟成長，而且與國土安全息息相關，因為絕大部分的重要基礎建設仰賴資通安全。資訊、通信及網路安全領域提供機會發展建立設備、系統、及高價值的產業包括軟體及服務業等。

II. 建議

1. 策略

- 1.1 在網路與資通安全市場上作充足投資，可因此帶來商機。若能提供額外經濟誘因將可促成資通安全市場與產業的發展，智慧財產權的研發及相關產業的投資。

- 1.2 制定適合台灣產業的資通安全產業發展策略，尤其強調具智慧財產權的技術開發，並創造相關生態鏈的產品與服務以得到獲利、成長及商機的最佳化，這將減低台灣以 OEM 為主的印象。
- 1.3 因資通安全對國家安全亦極重要，民間產業與軍方應彼此合作。民間部門應促進研發，訓練人員，並發展市場。
- 1.4 掌握突破性技術及市場變動時所帶來的新機會(例如RFID)。這些機會將為產業帶來新的技術，應用、智慧財產權及新一波的公司。

2. 投資

- 2.1 在資通安全的研究與發展議題上，必須要有學界與法人的支持，並透過國際合作來加速技術研發、人力資源與教育訓練課程的開發。
- 2.2 推動大眾在資訊、通信及網路安全上的警覺與認知。
- 2.3 善用國防部門的投資，使得其產出得以兼用於民間及國防的應用。

3. 基礎建設與應用的發展

- 3.1 在資通安全及行動生活的這兩個主題，包括創新性服務的發展與通訊基礎建設有相當程度的關聯性。事實上，在建構行動生活的願景上，建置一個安全基礎建設是相當重要的。因此，應利用這種關聯性，以獲利於網路與資通安全的投資。
- 3.2 對資通安全技術及產品的認/驗證應再檢討，使其與地方與全球產業與市場需求相符合。

4. 資通安全產業全球化

- 4.1 利用台灣的製造優勢與全球配銷通路進入國際市場。
- 4.2 創造可吸引國際系統整合領導業者與台商合作之獎助措施，以協助台商生產優質的安全產品及解決方案。

議題參：建設台灣成為亞太生技產業重鎮

I. 觀感

1. 這次議題三的各项題綱報告與建議，已充分顯示近年來政府以及相關人員的努力，並檢視台灣生技／醫藥產業的未來發展將面臨的各项挑戰。
2. 台灣缺乏一個獨立且高位階的「生技產業策略諮議委員會」，能分析評估台灣生技產業的現況，以統籌規劃未來方向，致使台灣生技產業的成就不若新加坡及韓國。
3. 台灣生命科學的發展現況，資源分散且缺乏有效的合作機制，因此在現有政府體制下責成一個有資源配置主導權的單位是必要的。
4. 由於生技產業高風險特色以及台灣投資者特有態度，使台灣生技產業難以籌募資金。
5. 在醫藥法規環境建置方面，本次報告並未提及真正的問題癥結點，雖然規劃的方向正確，但解決問題的決心不足，衛生署本身結構及態度觀念若無大幅度的改革，相關問題將會依然懸而未決。
6. 無可否認，先進法規體系攸關生醫產業發展的國際化，依據 1998 年生技產業策略會議的結論建議所成立的醫藥品查驗中心（CDE）亦已有六年之久，應有適時檢討整體法規體系之必要。
7. 醫藥品查驗中心之技術能力，與其吸引並維持有能力之人才密切相關，故與整體體系賦予醫藥品查驗中心之授權與認可程度亦有密切之關聯；若醫藥品查驗中心不被信任，將導致其技術專業的沉淪，則衛生署更加無法信賴醫藥品查驗中心。

II. 建議

1. 台灣生技醫藥產業的國際競爭力

- 1.1 建立一個國家政策位階的生技產業策略諮議委員會 (BioTaiwan Commission)，為台灣生命科學產業現況及方向作整體性的檢討評估及規劃，此委員會應能提出全面性的建議以改善生命科學產業發展，並訂定台灣成為亞太生技重鎮之目標。
- 1.2 在現有政府組織架構下任命一領導級的單位 (Bio Taiwan Authority, BTA)，賦與其配置生命科學資源的權責。
- 1.3 成立台灣生技大型投資基金(BioTaiwan Fund, BTF，規模自美金十億漸進至一百億)，以促進生技產業之投資及孕育發展，有鑑於生技產業為高風險產業與台灣投資人之心態，政府應主動扮演帶頭引導的角色。
- 1.4 成立一個高階的國家評議委員會(national review board)，在客觀均衡的精神下把關 BTA 與 BTF，評估結果應作為未來經費配置的參考。
- 1.5 明確檢視所有生技相關投資領域(技術平台、服務、資訊管理、產品等)，訂定優先順序以聚集力量。
- 1.6 移除政府研發機構與民間企業之技術移轉障礙，俾利國內外技術移轉及合作聯盟。
- 1.7 訂定國家政策中心願景與架構，使各環節領域相關研究機構、大學、醫院，與產業在共同的目標下能”各盡其責”，貫徹一致。這或許會導致某些組織重整與定位。

2. 健全臨床試驗體系

- 2.1 建立研究團隊及研究計畫以建置疾病及基因資料庫，俾利選擇疾病領域為台灣臨床研究的核心價值。
- 2.2 除癌症外也應設立其他研究團體及網絡，補助及協助建構基礎建設、研究過程及工具。鼓勵與區域/全球網絡的接軌、及新藥研發。
- 2.3 贊助全球性臨床研究論壇，以促進台灣臨床試驗研究醫師之能見度與意見領導能力。
- 2.4 建立至少一個專一性的研究中心從事轉譯醫學與”觀念之證實”。
- 2.5 促進台灣成為委外研究的亞太區域總部。
- 2.6 法規授權與行政責任之分配攸關臨床試驗研究系統之效率，需要嚴謹熟慮醫藥品查驗中心（或未來的 TFDA）以及衛生署其他相關附屬機構之整合再造。
- 2.7 應密切注意醫藥品查驗中心人員流動率的問題，宜建立清楚透明之管道以協助其專業人力之延攬與維持。
- 2.8 將醫藥品查驗中心改制為行政法人，賦予法律權責，即可履行其對於立法院與其他政府稽核系統之預算與諮詢的責任義務。
- 2.9 衛生署高層應該嚴肅考慮如何整合醫藥品查驗中心與藥政處的功能與結構。
- 2.10 藥品查核程序應比現制更為透明化，強烈建議將藥政處之藥品審核委員會改制為醫藥品查驗中心之諮詢委員會。
- 2.11 中醫藥委員會應專注於規範約束傳統中藥之實施，強烈建議將中藥新藥產品之審核任務移轉予醫藥品查驗中心。

3. 農業科技與醫療器材的發展策略

- 3.1 強化農業高科技專區之發展，並考慮設立旗艦產品之海外據點或研發中心。
- 3.2 在朝向客製化醫療器材發展的同時，資訊與人工智慧將是未來產品發展成功的重要因素，高度鼓勵‘行動生活’策略與‘醫療器材’策略之密切協調整合。

Topic 1: Mobile Life Industry and Technology Development Strategy

OBSERVATIONS

1. Technology development strategy for future mobile lifestyle

- 1.1 The goal of the project is ambitious and potentially promising. While the project exploits some of the unique advantages Taiwan offers (e.g., cell phone penetration and WLAN production), it must also overcome some of the weaknesses (e.g., insufficient emphasis on the software-centric approach to technology development).
- 1.2 The research directions outlined were somewhat narrow. They ignore some crucial elements, such as security/privacy and human interfaces.
- 1.3 While the idea of an open test-bed is laudable, it needs careful yet quick planning and execution. Discussion on the infrastructure development does not emphasize enough the need for a system architecture, nor the difficulty (both technological and cultural) to enable of cross-domain integration.
- 1.4 There is a lack of compelling applications that exploit Taiwan's unique advantages.

2. R&D strategies for iB3G technologies, services and applications

- 2.1 We highly endorse this high-risk and high-return flagship project, which can have significant impact on the ICT development in Taiwan:
 - 2.1.1 Breaking the OEM/ODM-centered mindset and move Taiwanese manufacturing industry up the technology food chain, and
 - 2.1.2 Promote cross-industry collaboration among handset manufacturers and service/content providers.
- 2.2 An important product of this project is IP, which should be carefully protected.

3. Promotion strategies for mobile life applications and services

- 3.1 The status report and development strategies for mobile life were clearly presented. In particular, projects such as building Taipei as the global no. 1 wireless broadband city is impressive. We support the continuation of the construction of the wireless broadband infrastructure aggressively. This will serve as the platform for applications and services development as well as a testbed for new technologies.
- 3.2 Even though 9 PWLAN demos were completed in 2003 and several are planned for 2004. The actual application deployment pace seems to be slow due to a lack of willingness from the digital content industry to actively participate. This is especially alarming since supporting environment for strategic service industries was a main theme of year 2003. It would be necessary to identify barriers and devise schemes to remove them.

4. Cooperation strategy between manufacturing industry and service

industry on M-life

There is not enough cooperation between the manufacturing industry and the service industry along the mobile life vision.

5. Building up an integrated legal environment of mobile living

- 5.1 There is a lack of transparency to the general public in the rationale and scope of DGT's policy decisions (e.g., what types of location-based information may be shared)
- 5.2 The proposal to increase efficiency by harvesting underutilized frequency spectrum is sensible.
- 5.3 The proposed legal entity to take charge of the construction and operation of digital content authorization platforms requires careful review. It is unclear how such platforms could work, or whether it should be left entirely with the private sector.

5.4 Privacy protection in mobile life is a big issue that requires thorough examination. To address this issue on location-based information is too restrictive.

6. Promote common standards & establish international certification/testing environment

6.1 When participating in international standards activities, there must be an explicit goal/agenda to benefit local industries.

6.2 The rationale for government participation in standards setting is not obvious. This approach runs counter to practices in the rest of the world.

6.3 CCRA does not seem to have much industrial significance, especially for local industries in Taiwan.

RECOMMENDATIONS

1. Technology development strategy for future mobile lifestyle

- 1.1 The government should evaluate the human resource demand/supply in strategic areas and develop short- mid- and long-term plans to address this problem.
- 1.2 The project must acquire a *systems* perspective, i.e., defining an overarching architecture, specifying how major software components should interact, etc.
- 1.3 The project should expand its technical directions to include security/privacy, human interfaces, information management, etc. In all cases, a technology roadmap must be established.
- 1.4 The project must conceive a set of compelling applications that exploits what Taiwan has to offer (e.g. healthcare, logistics).
- 1.5 It is important to analyze the risks associated with such large projects, and develop mechanisms to mitigate risks.
- 1.6 The project must develop key performance indicators (KPI) to track progress.

2. R&D strategies for iB3G technologies, services and applications

- 2.1 This project should be given all the necessary resources to move forward aggressively.
- 2.2 The government should create a mechanism to promote such innovative, high-risk projects.
- 2.3 R&D for iB3G should include considerations for security/privacy and human interfaces (combining sight and sound).
- 2.4 To protect IP and to promote adoption, the project is encouraged to participate in appropriate standards committee (e.g., IEEE 802.xx).
- 2.5 The recommendations made previously on human resource, compelling applications, government's role, risk management and KPI also apply here.

3. Promotion strategies for mobile life applications and services

- 3.1 We reiterate the importance of having a competitive and supportive environment that encourages innovative applications and services. The

government should treat the construction of the wireless broadband infrastructure in highly populated metropolitan areas as one of the nation's high priorities.

- 3.2 We endorse the development strategies for mobile life applications and services as presented, but a set of KPI is needed to evaluate the progress.
- 3.3 It is important to analyze the value chain of the mobile life industry, and find out all barriers that hinder the rapid growth of the mobile service/application eco-system (e.g., incentives for content providers, consumer acceptance, etc.) and address them effectively in collaboration with the industry. Some experience from Japan and Korea can be learned.
- 3.4 The government should take a cross-industry approach to promote the digital content industry.
- 3.5 It is important to analyze the consumer preference and behavior with respect to the mobile life services and applications so as to understand the demand side, and select a couple of key applications first.
- 3.6 The new M-Taiwan project can be used as a vehicle to realize the mobile life vision and objectives.

4. Cooperation strategy between manufacturing industry and service

industry on M-life

- 4.1 The government should facilitate the cooperation between the manufacturing industry and the service industry to form a development consortium.
- 4.2 The government should facilitate the cooperation between the IT industry and the traditional industry related to the mobile life vision.
- 4.3 The government should encourage the industry to form an IP consortium for mobile communications and applications.

5. Building up an integrated legal environment of mobile living

- 5.1 The DGT is encouraged to increase its openness to the general public on the process of policy decisions.
- 5.2 The proposed plan for recycling under-utilized frequencies should proceed.
- 5.3 DGT should carefully consider what the business model of the digital content distribution authorization platform is. It should decide whether

- 5.3.1 Private sector should be allowed to take charge (if needed), or
- 5.3.2 To first build a small, proof-of-concept pilot platform for some selected government-owned content.
- 5.4 On regulations concerning privacy protection related to individual's location data, consider listing only things that systems should not do. This negative listing approach is appropriate at present when tradeoffs between privacy, convenience and other considerations are not well understood yet.

6. Promote common standards & establish international certification/testing environment

- 6.1 Only standards efforts with clear and meaningful objectives should be supported.
- 6.2 This proposed CCRA effort should be put in the backburner. (Note that even the CC testing lab in US only does a small number of cases every year. It has not had much impact.)
- 6.3 The proposed effort on the international certification/testing environment establishment cannot start until there is a clear endorsement, support and guidance from local industry. When the case can be made, there should be an open competition to select the best organization or lab to develop and run the testing facility.

Topic 2: The Development Strategy and Promotion Measures of Safety and Security Industry

I. OBSERVATIONS

The theme and session consisted of 3 topics aimed at:

1. The development strategy for Security and Safety industries and technologies
2. The promotion measures of strategic safety and security industries
3. Enhancing development environment of safety and security industries

The panel believes that Safety and Security are two separate industries. In this context, Safety industry (safety equipment, etc) is a well defined and mature industry and may not offer too many new opportunities. There is a new emerging trend that involves safety of complex systems (such as programmable systems) but this is much less well understood.

Information, Communication and Network (ICN) Security industry on the other hand is a new industry that impacts the economy of Taiwan, has potential to create new companies and therefore economic development, and is crucial to homeland security because most of critical infrastructure relies on the cyber infrastructure. The area of ICN Security offers the opportunity to build equipment, systems and also other high value capabilities including software and services.

II. RECOMMENDATIONS

1. Strategy

- 1.1 The panel recommends making significant investments in network and information security because there is an economic opportunity. Provide additional economic incentives to develop the security market and industry, intellectual property (research and development), and investor community.
- 1.2 The panel recommends a clearly articulated strategy for security industry that builds upon Taiwan's inherent industrial strengths be developed. Emphasize technologies that leverage intellectual property. Create an ecosystem of related products and services around that intellectual property thereby maximizing overall margin, growth, and opportunities. This would help deemphasize the perception of Taiwan as an OEM.
- 1.3 Since Cybersecurity is also important for national security, the panel believes that civilian and defense ministries should collaborate with each other and the private sector to foster research and development, train people, and develop new markets.

- 1.4 Focus on disruptive opportunities (such as RFID) that have potential for both civil and defense sectors with the goal developing an array of new technologies, applications, intellectual property and industry in this area.

2. Investment

- 2.1 Research and development in security must be supported at universities and non-profit organizations. Leverage international collaborations to accelerate progress in research, manpower development, and curriculum development.
- 2.2 Promote and invest in ICN Security awareness and literacy for citizens.
- 2.3 Leverage the defense sector investments for areas with a potential for dual use (civilian and defense applications).

3. Infrastructure and Application Development

- 3.1 The panel believes that there is significant synergy between the themes of Security, Mobile Life, development of innovative services, and communications infrastructure. In fact, to accomplish the vision of Mobile Life it is very important to have a secure cyberinfrastructure. Therefore, the panel recommends that some thought be given to exploit this synergy and further leverage on the information and network security investment.
- 3.2 The panel recommends that Inspection and Accreditation of Security technologies and products be reviewed so that they are consistent with local and global industry and market needs.

4. Globalization of Security Capabilities

- 4.1 Leverage existing manufacturing capabilities and global distribution channels to enter into international markets.
- 4.2 Create incentives for local industry to work with leading global system integrators.

Topic 3: Construct Taiwan as an Asia-Pacific Biotech Hub

I. OBSERVATIONS

8. The reported current status and the suggestions made by various speakers in this session represent serious efforts by the government and other parties with vested interest to face the challenges of further advancement in biotech/pharmaceutical industry in Taiwan.
9. Lack of a high-level and independent organization to analyze the current status as well as to steer the future direction of life science enterprises in Taiwan makes Taiwan less competitive in biotech success, especially against Singapore and Korea.
10. With the fragmentation and inability to collaborate within the current life science establishment in Taiwan, a leader with budgetary authority within existing bureaucracy is needed.
11. The risky nature of biotechnology and unique attitude of Taiwan investors make access-to-capitals unusually difficult for biotech industry in Taiwan.
12. With respect to improving the regulatory environment, the reports and the proposals have not addressed the underlying issues. Without extensive reforms in the Department of Health, these half-hearted measures, while in the correct direction, may not be sufficient to solving the problems.
13. There is little disagreement that a modern regulatory system is vital to the development of a globalized biomedical industry. It involves highly complicated data, and, the government agency must possess the technical expertise to handle such data. CDE (Center for Drug Evaluation) of Taiwan was thus established in 1998 at the recommendation of SRB. Perhaps it is time to review the system after six years' existence.
14. The technical capacity of CDE is closely related to the ability to attract and retain competent staff, which is in turn dependent on the status and prestige of CDE as conferred by the system. A downward spiral may follow if degradation of technical expertise and the loss of trust by DOH continue.

II. RECOMMENDATIONS

1. The International Competitiveness of Taiwan Biotechnology and Pharmaceutical Industry
 - 1.1 Establish a high-level, independent, commission to review, assess and analyze the current status of life science enterprises in Taiwan.

Commission shall make comprehensive recommendations to improve life science industry in Taiwan, with the aim of positioning itself as a hub for Asia's biotech to compete successfully on global basis.

- 1.2 Establish within existing bureaucracy a leader for life science enterprises on the island. This leader should be empowered with budgetary authority.
- 1.3 Establish a meaningfully large biotech investment fund (US\$1B to US\$10B) to invest and nurture biotechnology industry. In recognizing the risky nature of biotechnology and unique attitude of Taiwan investors, it is imperative that the Taiwan government adopts a leading role in this fund.
- 1.4 Establish a high level, national review board as a watch dog in the spirit of check and balance. Their assessment shall serve as a reference to the budgetary approval.
- 1.5 Review all possible areas in biotechnology (platforms, services, information management, products, etc.) for investment, and define priority for focused effort.
- 1.6 Clear business development hurdles for easier license-in and license-out activities for both public and private sectors.
- 1.7 Provide central vision and framework, and enforce alignment of various institutions, agencies, universities, hospitals, and industry in their "areas of participation". This might lead to re-dimension, re-structuring, and re-engineering of certain organizations.

2. Enhance Clinical Trial System

- 2.1 Form a research team and fund research project to establish database on genomic and disease registry database to facilitate selection of disease areas as core value for Taiwan clinical expertise.
- 2.2 Establish collaborative study groups and network in addition to cancer, fund and help build infrastructure, processes, and tools. Encourage linkage to regional/global networks and contribution to drug development.
- 2.3 Sponsor global clinical symposium to promote visibility and opinion leadership of Taiwanese clinical research physicians.
- 2.4 Establish at least ONE specialized center for translational research and "proof-of-concept" studies.
- 2.5 Enable Taiwan as choice for Asian-Pacific regional headquarters of contract research organizations (CRO).

- 2.6 Alignment and reconciliation of CDE (or future FDA) and various offices in DOH (Department of Health) must be carefully thought through. The distribution of legal mandates and administrative /political liabilities between these entities may be critical to the efficiency of the system.
- 2.7 The turnover of CDE staff should be closely monitored. Clear pathways should be established to help recruit and maintain talents in this important agency.
- 2.8 Change the status of CDE from non-profit organization to that of Administrative Non-Government Organization (NGO) with legal authority to accompany the increase in its legal authorities, CDE shall assume responsibility to its own budget and report to Legislative Yuan and other Government auditing agencies in due course.
- 2.9 Ultimate integration of the functions and structures of BPA and CDE should receive serious consideration by DOH.
- 2.10 The drug application review processes should be made more transparent than the existing arrangement. The reform of the Drug Review Board of DOH/BPA by making it into an advisory role to CDE is highly recommended.
- 2.11 It is strongly recommended that the regulation of TCM *products* should be transferred from CCMP to CDE. CCMP shall regulate TCM practice only.

3. Developmental Strategy for Agrotechnology and Medical Device

- 3.1 Enforce the development of high-tech oriented, agricultural plantations and establish representative offices or R & D centers at strategic countries to explore international market for Taiwan products.
- 3.2 As we move toward customized medical device, the informatics will become a significant success factor to future product development. Close coordination between “mobile life” strategy and “medical device” strategy is highly encouraged.