

a legal basis for such a “report inventory” system through an expedited legislative process, and to appoint impartial third-party organizations such as the CPA Association of the Republic of China, the Consumers' Foundation, or other private groups to carry out the audits. This would put in place a permanent mechanism with appropriate supporting measures to address any future increase in the tobacco health surtax in a way that maintains market order and curbs illicit trading.

Although the competent authority – the DOH's Bureau of Health Promotion – several times confirmed the feasibility of carrying out a “report inventory” system, in the end the proposal did not materialize due to the “lack of legal basis.” Instead, a system of pasting price-identification labels on each package was adopted, a laborious process that delayed introduction of the new health surtax and caused the treasury to suffer a significant revenue loss. The pasting of price labels also caused great inconvenience to legitimate importers and downstream vendors, and involved an immense expense in terms of manpower and materials. Further, this approach led to considerable confusion in the marketplace – even disputes between retailers and consumers, since both old and new prices were shown on the labels.

Considering that the Tobacco Hazards Prevention and Control Act provides for the amount of health surtax to be adjusted every two years, similar problems are likely to recur next year unless action is taken now. The government should therefore proceed to prepare a bill as soon as possible for submission to the Legislative Yuan to establish the legal basis for implementing a “report inventory” mechanism.

### **Issue 3: Abstain from restricting the wording on tobacco containers and external packaging.**

In its circular of November 5, 2009 on “Prohibited Wordings in the Promotion or Advertising of Tobacco Products,” the DOH specifically bars the use of the following wording on tobacco containers or external packaging: “carefully selected,” “high quality,” “renowned,” “refined,” “limited edition,” “special collection,” and “special.” It goes even further to prohibit “any descriptive wording” on the tobacco container or external packaging.

With regard to that ruling, the following points are relevant:

1. As no such restrictions have been imposed under the law, the constitutionally protected right of freedom of expression should prevail. Whether under the Commodity Labeling Law, Tobacco and Alcohol Administration Act, or Tobacco Hazards Prevention and Control Act, no legal restrictions have been imposed on the packaging and design of tobacco-product containers. In addition, the containers and packaging used for tobacco products legally imported by legitimate importers are not specifically designed for the Taiwan market, and such controls would be contrary to international regulatory practice. Most fundamentally, the wording employed on tobacco-product packaging is the legal right of the tobacco industry, protected by constitutional guarantees of

freedom of speech and property rights

2. The factual descriptions on the packaging of tobacco products are not intended to mislead consumers, and are in line with regulatory restrictions.

The Tobacco Hazards Prevention and Control Act, like similar legislation in many other countries, restricts the wording that can be used in the promotion or advertisement of tobacco products, but does not prohibit any descriptive wording on tobacco-product packaging except – as in the case of phrases such as “mild” or “low tar” – when the wording may mislead consumers into believing that a particular tobacco product carries less risk to health. Wording on the packaging that does not generate any misleading effect remains legitimate under the applicable laws of Taiwan and other countries.

### **Issue 4: Exclude the tobacco health surtax from the base in calculating business tax.**

As of January 12, 2009, the law governing the tobacco health surtax was changed from the Tobacco and Alcohol Tax Act, for which the competent authority is the Ministry of Finance (MOF), to the Tobacco Hazards Prevention and Control Act under the jurisdiction of the DOH. In addition, recently passed amendments to the Tobacco and Alcohol Tax Act further substantiated the transfer of the legal authority by deleting certain provisions relating to the tobacco health surtax and leaving only the stipulation that other government agencies may “collect the tobacco health surtax on behalf of” the MOF.

In a press release dated November 4, 2009, the MOF stated that “funds generated from the tobacco health surtax are for designated purposes and are not considered to be in the scope of taxation.” Despite that interpretation, the amount charged to the consumer for the tobacco health surtax is also included in the base from which value-added and non-value-added business tax are calculated. This is inconsistent with the MOF's own pronouncements on the nature of the surtax, and the industry requests that the government address this issue by issuing clear guidelines to the collecting agencies that the amount of the surtax not be included in the taxable base for value-added and non-value-added business tax.

In July 2009, the Executive Yuan proposed an amendment to the Value-added and Non-value-added Business Tax Act, which are currently being considered by the Legislative Yuan. After passage of the amendment, consumers would not only have to pay the tobacco health surtax but also bear the burden of higher amounts to be paid for value-added and non-value-added business tax. As this step would represent double taxation and also ignore the distinction between taxes and surtaxes, we urge the Legislative Yuan not to approve this measure.

## **PHARMACEUTICAL**

For the research-based pharmaceutical industry, Taiwan has for some years been an extremely difficult market in

which to operate. As a result of the government's policy of conducting frequent Price Volume Surveys (PVS) followed by substantial price cuts, Taiwan now has the lowest overall drug prices in any major market – on average, the price of original drugs in Taiwan is only 28% of the level in the United States. The six rounds of PVS since 2000 have slashed prices by a total of NT\$50 billion (US\$1.58 billion), and a seventh PVS is currently under planning. Facing an unprofitable price level, manufacturers are frequently deterred from launching new and innovative drugs in Taiwan, leaving patients in this market without access to the most up-to-date treatments.

At the same time, this Committee is heartened by the prospect that solutions to these problems can be found due to the willingness of the Department of Health (DOH) and its Bureau of National Health Insurance to engage in meaningful dialogue on possible new approaches to drug pricing and reimbursement policy. Based on data from an economic model produced last year after extensive study, the industry is convinced that Taiwan could revise its pricing system to reward innovation without exceeding the projected NHI budget parameters. We appreciate the cooperative and open-minded attitude displayed by the health authorities in reviewing our proposals.

Another positive recent development was the inauguration at the beginning of this year of the Taiwan Food and Drug Administration (TFDA) under the DOH. We welcome the establishment of the TFDA and encourage it to seek to learn from the long experience of the FDA in the United States.

As explained below, we also recommend eliminating the PVS system – which has not succeeded in its objective of controlling the “pharmaceutical price gap” problem – and replacing it with an annual Drug Expenditure Target set in consultation with the various stakeholders.

These changes, together with the other suggestions in this paper, would markedly improve the business environment in Taiwan for the pharmaceutical industry, while also providing better healthcare for the Taiwan public and enabling the government to raise the effectiveness and financial stability of the NHI operation.

Given Taiwan's many advantages as a location for developing the biopharmaceutical industry and for conducting clinical trials, multinational drug companies look forward to the creation of market conditions in which they could increase their involvement and investment in this market.

### **Issue 1: Reform drug-pricing policy to reward innovation, and replace Price Volume Surveys with a Drug Expenditure Target system.**

The reimbursement price offered to new pharmaceutical products in Taiwan has steadily declined from the A10 (10 benchmark advanced economies) median to only 72% of the lowest A10 price in 2007-2008. The pricing system for new drugs does not currently reflect the degree of innovation of the products, which lowers Taiwan's attractiveness as a market for introducing new and innovative drugs.

Industry is currently engaged in a constructive dialogue with DOH and BNHI on reimbursement-pricing policy, however, as seen in two productive Pharmaceutical Innovation & Drug Policy Workshops held in July and October 2009. More such Workshops will be held. The dialogue has focused on how BNHI could incorporate innovation as a factor in its pricing and reimbursement policies so as to facilitate patient access to new and better treatments.

To test potential new approaches, the International Research-based Pharmaceutical Manufacturers Association (IRPMA) co-sponsored a project to produce an economic model for exploring the impact of various scenarios on patient access, the manufacturers, and the health insurance budget. Analysis of the resulting data shows that under most of the scenarios the BNHI budget over the next six years would be sufficient – without undertaking any additional major price cuts – to provide new innovative drugs with reimbursement prices at levels sufficient to encourage companies to launch in Taiwan the products currently in their development pipeline. Another finding of the study was that the periodic price cuts undertaken by BNHI in the past have not in fact contributed to holding down drug expenditures.

The industry hopes to achieve acceptance of the following guiding principles:

- Reward new drug innovation with fiscal responsibility.
- Utilize the A10 median as a reference.

The government has relied on the PVS mechanism as a key tool to try to eliminate the longstanding “pharmaceutical price gap” (the difference between the after-discount actual transaction price at which healthcare providers buy drugs and the much higher price at which they are reimbursed by BNHI). In the six PVSs and follow-up price adjustments carried out in the past, the magnitude of the price cut has grown 40-fold from NT\$500 million (US\$15.9 million) in 2000 to NT\$20 billion (US\$635 million) in 2009. In comparison, the drug budget over the same period has not even doubled. The PVS mechanism is extremely disruptive to the drug companies, healthcare providers, patients' access to drugs, and drug quality.

Following each reimbursement price adjustment, the hospitals continue demanding discounts from drug suppliers – as they seek to retain at least the same margins as they enjoyed previously – leading to a renewed price gap. The current PVS/price cut policy is therefore not the solution to minimizing or eliminating this problem.

As an alternative, the industry recommends amending the National Health Insurance (NHI) Law to set an annual Drug Expenditure Target and negotiated expenditure growth rate, which would become the basis for any price adjustments under the Pharmaceutical Benefit Scheme (PBS). The recently developed economic model co-sponsored by IRPMA shows that the need for a PVS can be eliminated under various scenarios. In addition to solving the “price gap” problem, the Expenditure Target approach will also save all stakeholders the resources spent in collecting and processing PVS data and

provide greater predictability for everyone.

**Recommendations:**

1. Revise the drug pricing categories now in use in line with IRPMA's proposal, so as to allow greater market segmentation based on innovation.
2. Exempt products newly added to the reimbursement list, particularly on-patent drugs, from price adjustments.
3. Eliminate the use of price volume agreements (in which companies are asked to rebate revenue to BNHI/DOH for sales exceeding an agreed-upon target for a given drug). Such agreements severely restrict market access for innovative medicine and penalize drugs that are successful in the market.
4. Amend the NHI Law to set an annual Drug Expenditure Target based on the actual drug expenditure in the previous year plus a negotiated growth rate. The law should also stipulate a rebate mechanism whereby excess expenditure would be clawed back by BNHI.
5. Involve the biopharmaceutical industry in negotiating the annual Drug Expenditure Target together with other stakeholders.
6. Before the NHI Law is amended, BNHI/DOH should take administrative approaches to bring the PBS price adjustment in line with the industry proposal.

**Issue 2: Liberalize procedures for Certificates of a Pharmaceutical Product (CPP) and accelerate the regulatory approval process.**

DOH has agreed to relax the CPP requirement for new drug registration, as Taiwan's competent review agency has already been established for over 10 years.

For many years, the pharmaceutical industry has urged that Taiwan's regulatory system adopt international norms – simplifying the CPP requirements and streamlining the entire administrative process. The aim is to provide patients with earlier access to new drugs. Since CPPs are required to be notarized by the Taiwan representative office in the issuing country, it adds considerably to the time needed to complete the processing. As a result, new-drug registration in Taiwan takes much longer than in the 10 reference countries or nearby Asian countries. The average approval time in Taiwan is 668 days, compared with 450 days in Singapore, 405 days in the European Union, 400 days in South Korea, 390 days in the United States, 360 days in Hong Kong, and 299 in Australia. Shortening that timeframe would significantly improve the attractiveness of the Taiwan market and manufacturers' ability to meet the needs of health providers and their patients.

DOH is now conditionally allowing manufacturers to file a New Drug Application for a New Chemical Entity without having a CPP in hand, but before license approval the manufacturer must either submit a source CPP together with two to three reference CPPs, or only the source CPP if it complies with the requirements under Drug Review

Guideline Article 38-1. But those requirements are extremely strict and entail a high degree of risk for the companies if not followed correctly.

In addition, to renew the product license every five years after the initial marketing authorization has been granted, the manufacturer is required to submit the source CPP or the manufacturing certificate from the source country plus a reference CPP. However, the CPP and manufacturing certificate may be unobtainable if the drug has been discontinued in the source country due to commercial considerations and the marketing authorization consequently withdrawn. This situation would necessarily lead to withdrawal of the marketing authorization in Taiwan.

**Recommendations:**

1. Speed up the regulatory approval/registration process. It would be helpful to create a TFDA/industry taskforce to identify solutions and develop a roadmap for achieving them.
2. Liberalize the CPP requirement:
  - Approve the New Chemical Entity without any source or reference CPP if in compliance with the requirements under Drug Review Guideline Article 38-1.
  - Accept one CPP or alternatively an approval letter from the regulatory agency in one of the 10 reference countries, which should be sufficient evidence of the quality, safety, and efficacy of the drug and its use one of the reference countries.
3. Remove the requirement that the CPP must be notarized by the Taiwan representative office in the issuing country.
4. Establish a system of fast-track designation and review for new drugs aimed at critical unmet medical needs or treating orphan diseases.
5. Ensure transparency through:
  - Face-to-face communications at review meetings.
  - Creation of a transparent review process, including Bridging Study Evaluation (BSE) reviews.

**Issue 3: Strengthen post-approval drug quality requirements to ensure consistent drug quality delivered to patients.**

In order to deliver to patients a drug with consistently good quality, a comprehensive post-approval regulatory system exists in most developed countries. The system includes advanced GMP (Good Manufacturing Practice) regulations and routine inspection, an active pharmaceutical ingredient (API) management system, and controls on any changes in the manufacturing process that might impact drug quality.

Taiwan has already established a good foundation in drug manufacturing standards by implementing GMP and cGMP (Current Good Manufacturing Practice) regulations, as well as a bioequivalence requirement before drug approval. But the current post-approval regulatory system is not sufficient to ensure drug quality compared to the well-established practices in advanced countries – for example, with regard to governing

changes in API sourcing. We urge DOH to strengthen the local regulatory system on post-approval variations in order to ensure patients' access to good quality medicines.

**Recommendations:**

1. Establish an API registration system.
2. Adopt international practice on regulations governing API source changes.
3. Strengthen the current drug-quality management system.

**Issue 4: Strengthen IPR protection through Patent Linkage and Data Exclusivity.**

Effective Patent Linkage and Data Exclusivity (DE) are critical components of an IPR protection regime for pharmaceuticals. With clear patent and DE expiry dates, both research-based and generics companies can make better decisions on investing in R&D and manufacturing, save resources otherwise wasted on unnecessary litigation, and continue the flow of innovative drugs to patients.

**Patent Linkage**

Taiwan still lacks an effective Patent Linkage system – a mechanism for taking the patent status of the drug into account when issuing regulatory approval to generic versions of this drug. In 2009, at least 35 patent-infringing drugs were approved in Taiwan, and many of them were subsequently included on the reimbursement lists. To date, only one element of Patent Linkage has been implemented – patent registration upon receipt of a product license by the originator. Other crucial elements, such as a certification process, notice to the originator of a generic filing, and automatic stay of drug approval, have not yet been adopted. These shortcomings undercut Taiwan's international reputation as a country committed to IPR protection and cause stakeholders to bear unnecessary costs.

For the past several years, the biopharmaceutical industry has called for legislation to establish an effective Patent Linkage system. The government has been reluctant to take this step, however, thereby failing to fulfill the requirements of Articles 28 and 41 of the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) under the WTO.

Furthermore, proposed changes to the Intellectual Property Law to permit generics companies to conduct registration trials without penalty for infringing on originators' patents would only exacerbate the issue. A more hostile IPR environment will increase the risk of litigation, reduce originators' willingness to introduce new drugs to the Taiwan market, and jeopardize patients' right to have access to innovative medications.

**Data Exclusivity**

The regime in Taiwan for Data Exclusivity – a system whereby the regulatory authorities refrain from granting approvals to generic versions of an original drug for a limited period of time – also has a number of shortcomings. It covers

only New Chemical Entity, or small-molecule, products, and not new indications and biologic, or large-molecule, drugs. Also, the period of protection is tied to the first approval granted outside Taiwan, not to the timing of the product's approval in Taiwan. These problems must be fixed if Taiwan wishes to encourage R&D in new indications (the extension of a drug to additional medical conditions) and new uses (e.g. new forms or dosages) of drugs.

When benchmarked against A10 countries, Taiwan is at the very bottom in terms of DE protection. For instance, the European Union provides 10 years of DE for both new chemical and biologic drugs and for pediatric applications of off-patent drugs, plus an additional one year for new indications, two years for orphan drugs, and six months for pediatric indications of a new drug. Canada provides eight years of DE for chemical drugs, six years for biologics, and an additional one year for pediatric indications. Japan provides eight years of DE through the "re-evaluation" period, and the United States provides five years for chemical drugs, 12.5 years for biologics, and an additional three years for new indications and one year for pediatric indications.

In considering modernization of its DE law, Taiwan can draw on the following two lessons. First, one of the major reasons why Canada amended its legislation in 2007 to increase DE from five to eight years was to remain competitive in the global R&D investment arena. Second, biologics are the next generation of life-saving and life-improving drugs, but because their development requires a longer time and greater R&D investment than small-molecule drugs, they need a longer DE period – hence, the 12.5-year DE for biologics in the United States.

**Recommendations:**

1. Enact laws and establish procedures to support implementation of Patent Linkage through NDA (New Drug Application) guidelines to effectively protect innovators' IPR.
2. Incorporate the following into the Patent Linkage system:
  - a. Certification process – whereby a generic applicant certifies the grounds for a claim of patent invalidity.
  - b. Notice to the originator of a generic filing – a requirement that the originator be notified by the generics company and DOH when an application is filed.
  - c. Automatic stay of drug approval – in case of a dispute, a mechanism to suspend the approval process is suspended for a stated period of time (30 months in the United States) until the parties reach agreement or the generic company proves the patent right is not affected or not valid.
3. Taiwan should provide DE for new drugs and indications as follows:
  - a. For Small Molecules (NCE)
    - five years.
    - three years for new indications / new uses.
  - b. For Large Molecules (New Biologics)

- at least eight years.
- three years for new indications / new uses.

### **Issue 5: Implement a rigorous system of Separation of Dispensing from Prescribing (SDP).**

The existing system at Taiwan hospitals requires staff physicians to prescribe medicines listed in the hospital formularies, which are selected through a process heavily influenced by the amount of profit to be gained by the hospitals. The government should build an environment in which hospital-staff doctors and pharmacists are able to make professional judgments based purely on the welfare of the patient without being restricted to choosing from among drugs procured for financial considerations. To accomplish that, DOH and BNHI should consider how hospitals and general practitioners can be compensated well enough so that they do not have to rely on profits from drug dispensing. The role of dispensing should be primarily in the hands of community pharmacists, who can provide consultation to patients on medications and healthcare.

Implementation of SDP is crucial to improving the quality of pharmaceutical care to patients. It would empower physicians to prescribe the most appropriate medications based on their professional expertise. It also creates a mechanism to ensure that pharmacists review patients' prescriptions to prevent any duplication or contraindication between prescriptions from different physicians or hospitals. Recognizing the difficulty of making an abrupt change in current practices, the industry supports the idea of implementing SDP in phases, and it offers to aid this process by developing the necessary distribution systems to ensure that the community pharmacies are properly served.

Good progress has been achieved in the ongoing project to release prescriptions from DOH hospitals and Taipei Municipal hospitals to the community pharmacies. This program has provided an excellent model for building cooperation among the medical, pharmaceutical, and pharmacy sectors, and we hope to see it more widely adopted.

#### **Recommendations:**

1. As AmCham has requested for several years, an SDP roadmap should be adopted, so that the direction of implementation is clear, even it must be carried out in stages. An integrated implementation plan should include measurements of SDP compliance as part of the hospital accreditation system. In addition, hospital fees should be adjusted to eliminate reliance on profits from drug dispensing, and the release of hospital outpatient prescriptions to community pharmacies should become mandatory.
2. More extensive education should be provided to the general public about the benefits of implementing SDP. Patients should be helped to understand the crucial importance of SDP in improving the quality of medical care and decreasing the wastage of healthcare resources by

reducing the volume of unnecessary medication – resulting in long-term savings for the NHI budget.

3. The government should provide sufficient funding to improve the community-pharmacy infrastructure in preparation for meeting SDP demand.
4. Clear regulations should be adopted to ensure good dispensing practice by the pharmacies and to prevent drug substitution without the doctor's consent.
5. The government should periodically publish data on the amount of prescriptions released by individual hospitals.

## **REAL ESTATE**

The Real Estate Committee respectfully submits the suggestions of our members on how to attract investment into the property market and stimulate urban regeneration. We request that the government actively consider the views of the real estate community, so as to create a vibrant real estate market that serves the interests of the public and also provides investors – including foreign investors – with a fair level of return.

The Committee looks forward to developing meaningful dialogue with government agencies to further improve the market.

### **Issue 1: Ease regulations affecting real estate acquisitions by overseas Chinese from Hong Kong and Macau.**

Financial Supervisory Commission (FSC) regulation #770259495 is still on the books regulating applications by overseas Chinese from Hong Kong and Macau for consumer mortgage loans in Taiwan. The regulation stipulates the borrower qualifications, application process, loan amount, loan-to-value ratio, loan tenor, and the amount of security to be provided by overseas Chinese from Hong Kong and Macau – terms normally governed by individual commercial banks' credit policies in accordance with their credit appetite.

In the 2009 *White Paper*, we urged the government to abolish the 80% ceiling on the loan-to-value ratio and the maximum NT\$5 million (US\$159,000) loan amount under this regulation, as these limit the willingness of overseas Chinese from Hong Kong and Macau to invest in the Taiwan property market. The FSC responded that after consulting with the commercial banks, it would initiate a proposal to abolish those restrictions. But since the limits remain in place, we again call on the FSC to abolish regulation #770259495, so that overseas Chinese from Hong Kong and Macau may be treated as ordinary foreigners, thus encouraging property investments from Hong Kong and Macau.

### **Issue 2: Allow Chinese capital to be invested in commercial properties.**

Cross-Strait relations have improved greatly in the past several years. Taiwan and China signed a series of agreements in 2009 and are currently negotiating an Economic Cooperation Framework Agreement (ECFA). The Committee