

is reviewed every two years by the central regulatory authority and the Ministry of Finance. We urge the relevant authorities to begin discussion with the industry on a long-term solution to the collection problem as soon as implementation of the current round of health surtax increase is completed.

Issue 4: Increase penalties to combat smuggled and contraband tobacco products.

In line with previous experience in this and other markets, the 2006 increase in the health surtax resulted in increased smuggling, the heavy importation of illegal tobacco products, and a large-scale build-up of inventory to reap windfall profits (“forestalling”). Additionally, the emergence of small, low-priced brands based on an “import few, smuggle many” business model has had a serious effect on the stability of the legitimate Taiwan cigarette market, as evidenced by the MOF’s annual national investigation reports.

Cigarette smuggling negatively impacts government revenues as well as the legitimate market, and may undermine citizens’ health. But the current penalties for importing, selling, or transporting smuggled inferior cigarettes that may undermine human health are not very steep – a fine of NT\$500,000 to \$2 million or two years’ imprisonment. We therefore recommend amending the Taiwan Alcohol and Tobacco Act (TATA) to raise the penalty for smuggling and selling contraband tobacco. We also recommend increasing the portion of the health surtax that is allocated to rewarding successful enforcement against cigarette smuggling.

PHARMACEUTICAL

The Committee appreciates the willingness and commitment of the Taiwan government to continue to dialogue with its member companies and others in the research-based pharmaceutical industry. This communication will help achieve the common goal of both government and industry of enabling patients to live longer, healthier, happier, and more productive lives. The National Drug Policy Conference conducted by the Department of Health (DOH) on December 31, 2008 clearly demonstrated the government’s determination to develop sensible drug pricing and reimbursement policies with industry involvement. The Committee urges the government to follow up by formulating concrete policies to realize the objectives set at that conference.

In this paper, we would particularly like to draw the government’s attention to Issue 1, on rewarding innovation by creating a more transparent and predictable pricing and reimbursement system, and through a speedy approval process. This would be a fundamental step toward increasing patients’ accessibility to new drugs, the priority goal of the National Drug Policy Conference.

Other challenging issues relate to Price-Volume Surveys (PVS) and the adoption of a standard contract, the Separation of Dispensing from Prescribing (SDP), and intellectual property rights (IPR) protection. These are all long-term

concerns that have appeared repeatedly in the annual *Taiwan White Paper*. Progress toward resolving them has often seemed frustratingly slow. The Committee has been encouraged, however, that in recent years key pharmaceutical issues have been included in the U.S.-Taiwan bilateral trade negotiations known as the Trade and Investment Framework Agreement (TIFA) talks. Two task forces have been formed to explore various aspects of the problems. Although unfortunately no TIFA talks were held last year, the Committee hopes that the Obama administration will schedule 2009 negotiations as early as possible.

We urge the relevant government agencies to work with the Committee and industry in general in developing solid policies to address the above issues and accomplish the objectives of the National Drug Policy Conference.

Issue 1: Reward innovation through a more transparent and predictable pricing and reimbursement system and a speedy approval process.

The Bureau of National Health Insurance (BNHI) maintains that its policy is to review applications for new drug/indication pricing and reimbursement within three months of submission and to set reasonable reimbursement prices and guidelines within six months of submission. In practice, however, that timeframe is not always adhered to – and in more and more cases the decision is delayed indefinitely. At the same time, many applications are approved with such a low price that it is impossible to launch the product.

According to BNHI data, new product reimbursement prices in Taiwan have dropped from 80% of the A-10 median (based on the prices in 10 benchmark advanced countries) during the 1996-2002 period to only 51% of the A-10 median in 2007-2008. Furthermore, on the average, the new drugs obtained only 72% of the lowest A-10 prices in 2007-2008.

The decision-making process has also become less transparent and predictable to the industry. Price-Volume Agreements and Health Technology Assessment (HTA) have been used as tools to exclude certain products from the market or prolong the reimbursement process.

For the sake of rewarding innovation and ensuring that Taiwan patients are not deprived of access to those innovative drugs, the industry strongly recommends that the government adopt the following measures:

- Reimburse innovative drugs at the A-10 median price.
- Consult with industry, clinicians, and patient groups to set a mutually agreed-upon definition of “Innovation” based on reference from other advanced countries.
- Pledge that BNHI policies – with regard to Price-Volume Agreements, Risk Sharing, and Pay for Performance, for example – will be based on patient benefits, scientific evidence, and a legal foundation rather than only on cost containment objectives.
- Increase the speed and transparency of the pricing and reimbursement process, for example by sharing with the subject company the Product Review Report (PRR)

submitted to BNHI by the Center for Drug Evaluation, so that the company has the chance to present its case at the meeting.

Issue 2: Reform the Price-Volume Survey/price-cut system.

We appreciate the DOH's convening of the National Drug Policy Conference last December. Although that forum was a very positive development, it left unanswered how the chronic pharmaceutical issue of the government's Price-Volume Surveys (PVS) and subsequent price cuts would be addressed.

The periodic implementation of a PVS is the key tool the government has used in attempting to eliminate the long-standing "Price Gap" (the difference between the reimbursement price paid to healthcare providers by the BNHI and the much lower price those providers actually paid for the drugs after discount). But the gap never disappears, since following each reimbursement price adjustment, hospitals are free to continue demanding discounts from drug suppliers in hopes of retaining the margins enjoyed previously. The result amply demonstrates that the PVS/price cut policy is not the solution for minimizing or eliminating the Price Gap.

A further problem is that the PVS and its price-adjustment methodologies unfairly benefit highly discounted products due to the use of a "grouping" mechanism. The market prices of highly discounted products are grouped with less-discounted products to set the Group Weighted Average Price for the new reimbursement price. These mechanisms unfairly force producers to reduce prices based on another product's discounting policy. Moreover, the price-cut methodology gives an advantage to highly discounted generics by setting a floor price at 85% of the originators' new price, no matter how much discount was given to the hospitals. By ensuring that the generics can continue to enjoy a high reimbursement price, the floor-price protection discriminates against competing research-based products.

The current PVS mechanism lowers drug prices both while they are patented and after patent expiry. This is neither fair to the research-based industry, nor does it comply with the consensus reached at the National Drug Policy Conference to improve the accessibility of new drugs for patients. When prices are so low as to be unprofitable, companies may find it necessary to withhold them from the market rather than risk affecting the reference price in other markets; the loser is the patient.

To remedy these problems, the Committee recommends the following:

- Revise the overall drug policy (known as PBS for the Pharmaceutical Benefits Scheme) to recognize and reward innovation, eliminating the need for PVS.
- If PVS is continued, establish an audit system (to check both purchasers and suppliers) conducted by a certified third party or parties to ensure the accuracy and transparency of submitted price data, and also put in place clear penalties for intentionally reporting fraudulent data.

- Implement a mandatory "standard contract" system at all levels of hospitals/purchasers/drug suppliers to effectively prevent the continuing request for discounts. Until legislation is enacted to require nation-wide adoption of such standard contracts, phase in the system immediately by means of an administrative order.
- Set a mutually agreed-upon timetable between government and industry for eliminating the Price Gap by reforming the drug pricing and reimbursement policy.

Issue 3: Implement Separation of Dispensing from Prescribing (SDP).

The existing system at Taiwan hospitals binds medical doctors to prescribe medicines listed in the hospital formularies, which are selected through a process heavily influenced by the amount of profits 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. The DOH and its BNHI should consider how to compensate hospitals and general practitioners 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.

Toward this end, the Committee recommends:

- Government establishment of a roadmap for full implementation of SDP on the basis of a clear timeline. The 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.
- Provision of more extensive education 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 through a reduction in the volume of unnecessary medication.
- Sufficient funding from the government to improve the community-pharmacy infrastructure in order to meet the

standards that SDP will demand.

- The development of clear regulations to ensure good dispensing practice in the pharmacies, including rules against generic substitution without the doctor's consent.

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

Patent Linkage

Taiwan lacks a Patent Linkage system, which means that the DOH and BNHI do not take patent-holders' intellectual property rights into consideration when issuing drug licenses and granting reimbursement prices. Under a revision four years ago to the Pharmaceutical Affairs Law, the Taiwan government asks patent-owners to register their patents upon receiving product licenses; thus, data similar to the Orange Book System in the United States is available. That change is meaningless, however, without a Patent Linkage system in place. For the past few years, industry has called for legislation to establish such a system, but the Taiwan government has been consistently reluctant to take this step.

Furthermore, the government's Intellectual Property Office (TIPO) is proposing to amend the Intellectual Property Law to broaden the safe harbor for generics by permitting them to conduct registration trials without penalties for infringing on originators' patents. This change would significantly undermine the rights of innovator companies. Introduction of a Patent Linkage mechanism would ameliorate the situation by preventing registration of a generic form of a patented medicine while the patent is still valid – thereby avoiding unnecessary litigation and confusion. According to a recent industry survey, the current government regulatory approval process has led to potential patent infringement in some 52 cases. If this situation continues, it will undermine originators' willingness to introduce new pharmaceutical products into the Taiwan market and jeopardize patients' right to have access to new medications.

Data Exclusivity

In addition, the value of innovation for new indications should be protected, but the current regulatory data protection does not cover new indications. Data Exclusivity for new indications would equally benefit both international and local R&D-based companies, rewarding them for their efforts in developing new indications.

The Committee recommends the following:

- Establish laws and procedures to support the implementation of Patent Linkage through NDA (New Drug Application) guidelines to effectively protect patent-holders' IP rights.
- Include in the system notification to the originator by the generic company and the DOH when an application is filed, as is done in the United States through the Food and Drug Administration's Orange Book procedure.
- When an originator considers that its IPR has been violated and takes legal action to protect it, require the

DOH to suspend the NDA review until the legal case is resolved.

- Enact legislation to provide Data Exclusivity for new indications.

Issue 5: Strengthen quality requirements and streamline the regulatory process.

Drug Quality

In the discussion at the recent National Drug Policy Conference, one key focus was how to ensure drug quality. Taiwan has already established a good foundation on drug manufacturing standards through implementing the GMP and cGMP standards, and a bioequivalence requirement has been in place for products with a higher reimbursement price. Due to differences in the active ingredients and excipients (inactive ingredients used as carriers), however, these measures are not sufficient to ensure the quality and efficacy of generic drugs. To assure patients' access to quality medicines, it is essential to strengthen local regulatory requirements to bring them in line with international standards.

CPP/BSE

The industry seeks continuous improvements in the regulatory system so as to expedite the launch of innovative products in Taiwan. In 2006, DOH substantially raised the new-drug-registration review fee, while committing to speed up the approval process. But product license approvals are still being significantly delayed due to the time-consuming requirement that companies submit three Certificates of Pharmaceutical Product (or two CPPs if the sourcing country is on the A10 list of 10 advanced countries) and have them notarized by a Taiwan representative office in the country in question. The requirement for product license renewal that a CPP be obtained from the sourcing country raises further problems. It is not always feasible, since many products are not sold in the sourcing country due to commercial decisions.

Bridging Study Evaluations (BSE) are conducted to demonstrate that there are no ethnic differences in the impact of a new drug. Unless a waiver is granted, that could further delay the product license for up to two years. For reasons that are unclear, the BSE waiver rate has been erratic, decreasing from 86% in 2002 to 44% in 2005 and then rising to 65% in 2007. This fluctuation raises issues of transparency and predictability.

The Committee offers the following suggestions:

- Establish a system to track and regulate manufacturing changes after license approval as a means of ensuring consistent drug quality. The system could be modeled on SUPAC (Scale-Up and Post-marketing Approval Change) in the United States and the European Medicines Agency (EMA) Post-Marketing Authorization.
- Reduce the number of CPPs needed for NCE approval to a single certificate issued by one of the 10 reference countries.

- Eliminate the requirement that a CPP from the sourcing country must be submitted for new chemical entity (NCE) approval, new indication approval, and license renewal (instead accepting one CPP from one of the 10 reference countries).
- Accept an approval letter or positive opinion from an overseas agency's website to expedite the approval process.
- Remove the requirement that the CPP must be notarized by the Taiwan consular office in the country in question.
- Approve NDAs without any CPP when any two phases of the Phase I, II, and III clinical studies were conducted in Taiwan and met DOH requirements as per the 6-28 Public Announcement.
- Waive the need for a BSE if one (phase I, II, or III) of the clinical studies was conducted in Taiwan and the enrolled subjects met DOH requirements as per the 6-28 Public Announcement.
- Also waive the BSE in the case of new drugs for treating critical unmet medical needs and rare diseases.
- Publish the DOH Drug Review Committee meeting minutes regarding NDA and BSE cases to improve transparency.

REAL ESTATE

The global economy continues to suffer through a crisis of historic proportions – one that has also had a severe effect on the Taiwan economy. The collapse of the real-estate-backed sub-prime mortgage market in the United States – commonly recognized as the major cause of the current global economic crisis – underscores the importance of real estate to a healthy economy. A free and open real estate market, appropriately regulated, is essential in stimulating the economy and bringing about sustainable development.

The Real Estate Committee was established during the past year in order to focus greater attention on Taiwan's real estate market and its impact on the economy as a whole. The recommendations below are offered in the spirit of improving the health and efficiency of Taiwan's real estate market and thereby benefiting the overall economy.

Issue 1: Ease regulations affecting real estate acquisitions by overseas Chinese and foreign investors.

Regulation #770259495, issued by the Ministry of Finance on September 3, 1988, is the only regulation in Taiwan regarding consumer mortgage loans that applies exclusively to overseas Chinese from Hong Kong and Macau. The regulation stipulates the borrower qualifications, application process, loan amount, loan-to-value ratio, loan tenor, and the amount of security for overseas Chinese from Hong Kong and Macau – terms normally governed by individual commercial banks' credit policies in accordance with their credit appetite.

The 80% ceiling on the loan-to-value ratio and the maximum NT\$5 million loan amount limits the willingness of overseas Chinese from Hong Kong and Macau to invest in the

Taiwan property market. Overseas Chinese from these two locations are the best potential overseas investors for Taiwan real estate, due to their geographical proximity and similar cultural background. We urge the authorities to abolish this regulation so as to encourage property investments from residents of Hong Kong and Macau.

In addition, Articles 17 and 18 of the Land Act restrict the types of land that can be owned, transferred, or leased to foreigners. Another clause, Article 19, stipulates the types of property that can be owned by foreigners on the condition that it is for their own residence or for investment or charitable purposes. These regulations, which are onerous and also difficult for potential foreign investors to follow, reduce foreigners' willingness to invest in Taiwan property.

In view of the potential stimulus to the economy of encouraging foreigners to invest in the Taiwan property market, the Committee recommends that the government seek a legislative amendment to liberalize the relevant portions of the law, especially the prohibited investments stipulated in Article 17. For example, while foreigners are not allowed to invest in the types of property listed in Article 17 due to national security reasons, there is no good reason to prohibit them from leasing such property under terms set to minimize any national security risks. The Committee also suggests adding a clause in Article 17 allows foreigners to invest in property if approved by the competent authorities on a case-by-case basis.

Issue 2: Allow PRC enterprises to enter the Taiwan property market.

The Committee applauds the government for the gradual normalization of cross-strait relations in such areas as direct air and sea transportation, direct postal service, and the opening of tourism to Taiwan by Chinese visitors. This trend should also be extended to investment from China in Taiwan real estate, particularly as the Beijing government is encouraging PRC enterprises to invest in Taiwan. The Committee urges the Taiwan government to adopt regulations along the following lines so as to enable PRC companies to enter the Taiwan market:

1. Permit PRC companies to establish offices in Taiwan.

The "Regulations on Permitting People of the Mainland Area to Acquire, Create or Transfer the Property Rights of Real Estate" promulgated in 2002 stipulates that PRC companies that have set up offices in Taiwan may purchase certain types of properties here. But since PRC corporations have so far not been allowed to establish offices and start operations in Taiwan, China-based companies are in practice unable to acquire any property on the island. Allowing PRC companies to set up branches or subsidiaries in Taiwan would not only open opportunities for real estate sales but would also benefit the island's office leasing market.

2. Relax regulations on the purchase of property by PRC companies. As mentioned above, a regulation permitting