

encourage an increased IT budget for purchasing legitimate software so that government units can set an example for the private sector in terms of IPR protection and the promotion of proper business practices.

Issue 6: Step up enforcement against smuggled and counterfeit goods.

A position stated annually in this *White Paper* is that the Department of Health and the Council of Agriculture need to establish more effective monitoring and enforcement of pharmacies and agro-chemical vendors, respectively, to better protect against smuggled and counterfeit goods. There should be an aggressive suspension of relevant licenses of those vendors found trading in contraband or counterfeit product.

The Committee also applauds actions taken by the Spirits and Tobacco Sections of the Treasury Bureau, Ministry of Finance, in targeting tobacco and spirits smuggling and counterfeiting at the local and distribution level. Their actions, however, are not enough. Millions of dollars in government and tax revenue is lost each year through sales of potentially unsafe products by these spirits and tobacco smugglers and counterfeiters.

In addition, we applaud the efforts, especially over the past few years, of the Intellectual Property Task Force and the National Police Agency on counterfeit and pirated goods. These organizations have, usually independently, taken hundreds of actions in the last year against on-line sales of counterfeit products. We are concerned that there appears to be less focus in the last three years, and far fewer actions, on shops, markets and street vendors of counterfeit and pirated products. We hope that these enforcements bodies will in the coming year orient more of their activities to the neglected areas.

Issue 7: Continue to improve campus IPR protection.

The Committee welcomes the efforts of the MOE and TIPO in jointly addressing concerns about campus IPR protection by holding publicity events and seminars at colleges and universities throughout 2008. We have been encouraged by the progress regarding two types of violations – the illegal copying of textbooks on campus and the illegal downloading of copyrighted material using the MOE-sponsored Internet service provider TANet – although further actions need to be taken to maintain the momentum.

We are encouraged by the MOE policy announced on November 25, 2008 that forbids (with certain exceptions subject to approval) the use of P2P file-sharing software on the TANet that could be used to download pirated software. A recent survey, however, indicated that more than 20 colleges and universities also subscribe to ADSL access services from private ISP providers for their faculty members and for students in dormitories. These ADSL users may not be covered by the MOE's monitoring of the use of illicit P2P software. The Committee therefore urges the MOE take all necessary steps to ensure that the abovementioned policy is also fully applied to ADSL users.

MEDICAL DEVICES

The Committee is delighted that the relevant governmental agencies have responded positively to several of the issues we raised in the 2008 *Taiwan White Paper* and have taken appropriate action to improve the business environment in this industry. For example, the medical device section of the Bureau of National Health Insurance (BNHI) has worked closely with industry concerning the reclassification of special medical devices and on the price-cut issue. The Bureau of Pharmaceutical Affairs (BOPA) of the Department of Health (DOH) has provided us with needed assistance in developing registration guidelines for In Vitro Diagnostic Devices, specifying expiration dating on medical devices, and clarifying regulations and laws where necessary. We appreciate their efforts in making these needed changes. In addition, after several discussions with the Bureau of Foreign Trade and the Industrial Development Bureau, both under the Ministry of Economic Affairs, selected medical devices manufactured by international companies in China are now allowed to be imported. This regulatory revision helps to align Taiwan with the global market.

Nevertheless, as several other issues still remain unresolved, it is important that this kind of positive collaboration between government and industry continue. The outstanding issues include the need for an independent regulatory agency with specific sets of regulations governing medical devices, establishment of guidelines for the review and management of direct-to-consumer advertising, greater openness and communication with industry in setting reimbursement procedures, and permission to import additional medical devices made by multinational firms in China.

Below, we present detailed recommendations concerning these issues.

Issue 1: Create an independent regulatory body and regulations for medical devices.

While specific regulatory agencies and laws are in place for medical devices in the United States and the European Union, in Taiwan the review and regulation of medical devices comes under the jurisdiction of BOPA and the governing statute is the Pharmaceutical Law. The need for a separate law and oversight unit for medical devices is clear. The medical device industry is fundamentally different from drug manufacturing, and cannot be effectively managed by an agency whose expertise is in drug regulation and by a law borrowed from another industry and then modified.

For the sake of the medical device industry's growth and development, the Committee welcomes the plan to establish a new agency under the DOH, the Taiwan Food and Drug Administration (TFDA), as an opportunity to place the regulation of medical devices on a more specialized and rational basis. In this regard, we hope that the TFDA will follow the organizational model of the U.S. FDA so as to ensure effective management. Along with this change,

increased manpower needs to be assigned to reviewing medical devices and their professional quality enhanced, and the new organization should commit to aligning its policies and regulations with international standards.

We also recommend that the government make the following changes in its current review practices for medical devices:

1. *Until a new law specifically governing medical devices can be enacted, expand the definition of “medical device manufacturers” in Article 18 of the Pharmaceutical Affairs Law, which loosely defines them as firms engaged in assembling, producing, wholesaling, retailing, or exporting medical devices.* The new definition should clearly include companies that bear the legal responsibility for the marketed device, as well as those that can provide post-marketing product surveillance. Outsourced manufacturing has been a well-accepted model worldwide. Advanced nations such the United States and members of the European Union accept certification documents issued by legal manufacturers and those who can conduct post-marketing surveillance.

Unlike its Western counterparts, Taiwan requires separate registrations of all the contract manufacturers involved in producing an identical medical product and also requires free-sale certificates from their governments. This practice not only alienates Taiwan from the international regulatory community, it also increases the burden of bureaucracy and paperwork for local agents and distributors.

The Committee recommends that DOH recognize the company bearing the legal responsibility and able to conduct post-marketing surveillance as the designated manufacturer for each particular medical device. We also suggest reducing the number of documents required for Quality System Documentation (QSD) and certification, which could be done even before revision of Article 18 of the Pharmaceutical Affairs Law.

The current definition of “medical device manufacturer” in Article 18 is based on the outmoded thinking of “one-product-from-one-manufacturer.” This mentality is the main reason why Taiwan has not yet closed the gap between its regulations and the international requirements for medical device registration. It is also the source of great frustration for many foreign medical-device firms. The Committee therefore urges DOH to bring Taiwan’s provisions regarding multinational contract manufacturing in line with those of the Global Harmonization Task Force (GHTF), a group established to encourage international convergence in regulatory practices for medical devices.

2. *Improve communication with industry and third parties to raise the effectiveness of the management and registration of medical devices.* DOH collaborates with third parties in assessing medical devices for product registration. In some cases, confusion occurs when DOH and the third-party experts have differing interpretations of assessment standards, with the result that product registration is stalled. Regular and close communication

among DOH, field experts, and the device companies is urgently needed in order to build consensus and heighten efficiency in the product review process.

3. *Publicize the registration guidelines on In Vitro Diagnostic Devices (IVD).* In 2008, the Committee worked in conjunction with BOPA and the Center for Measurement Standards of the Industrial Technology Research Institute to develop a set of guidelines for the review and management of IVD registrations. The results have not yet been released. Early announcement of these guidelines by DOH would greatly assist the device companies in facilitating their adjustment to the new measure.

Issue 2: Develop guidelines for the management and review of consumer advertising.

Considering the flood of direct-to-consumer advertisements (DTCA) for medical products in the media, the public deserves more access to accurate information on the devices they use. Since advancing public health is part of the medical device companies’ social responsibility, the Committee offers to work with DOH to develop medical-device DTCA guidelines that stress industry self-discipline and effective implementation. Our suggestions are as follows:

1. *Publicize management and review principles for medical-device advertising.* The Guidelines for Drug Advertising Management developed by the Taiwan Pharmaceutical Marketing and Management Association could be used as a blueprint to develop and implement management and review principles for medical-device advertisements. Such principles would help establish objective review standards, set the direction for management responsibility, and provide a professional review framework.
2. *Form a review advisory board comprising third-party experts and professionals.* Bringing in third-party experts to shoulder part of the responsibility for review and supervision can help develop a more professional review mechanism. These experts can also help bridge the gap between industry and government, promote self-discipline on the part of the medical-device companies, and ensure accuracy in the advertisements.
3. *Eliminate the pre-approval requirement for advertising messages and replace it with industry self-regulation.* For the near-term, pre-approval of promotional pieces should be limited to a select number of medical devices that may put consumers at risk if used inappropriately – for example, contact lenses. For the longer term, the objective is to eliminate the need for any DTCA pre-approval requirements by putting in place a complete industry-run management scheme for review, supervision, and punishment, and by instituting an industry code that all medical-device companies will commit to respect. Self-discipline on the part of the medical device companies would improve the quality of their promotional activity – including the education of consumers on the selection and safe use of medical devices – while reducing administrative costs.

Issue 3: Revise reimbursement schemes to maintain healthcare quality.

To meet the healthcare needs of an aging population, BNHI will need to upgrade its service in both scope and depth. But as the government's budget deficit continues to mount, funding for healthcare will be constrained and the quality of the medical service provided may suffer. How to maintain a proper balance between the quality of care available to patients and the state of government finances will become an increasingly serious issue as the population ages, increasing the need for medical devices. The Committee offers the following suggestions to BNHI:

1. *Partner with the medical-device industry in the provision of medical service and establish a communication channel for regular dialogue.* As the medical-device industry plays a key role in the entire healthcare system in Taiwan, regular communication and collaboration between BNHI and the industry will help secure greater support in the making and implementation of health-insurance policy. This will be particularly important for the planning and execution of major policies such as the introduction of a DRG (diagnosis-related groups) system for reimbursement payment in Taiwan.
2. *Increase the number of items covered by the Balance Billing scheme.* Given the financial strain BNHI is experiencing, the Committee once again strongly urges BNHI to increase the number of products included in the Balance Billing scheme, which gives patients the option of paying an additional amount to gain access to certain devices, or types of devices, not otherwise covered under National Health Insurance. In that way, consumers will have greater choice and the ability to benefit from high-tech medical devices, while BNHI's financial pressures can be eased.
3. *Set transparent reimbursement guidelines for new medical devices and review decisions in meetings with participation jointly by industry, outside experts, and BNHI officials.* The current reimbursement practice for medical devices is not based on clear criteria. When a device is submitted for reimbursement application, the review often occurs in closed-door meetings with outside experts. Device companies are not invited to participate, giving them no opportunity to offer explanations during the review process. Consequently, when a new device is rejected for reimbursement, the company must re-apply, starting the whole process over. The reimbursement review has thus become a costly and time-consuming procedure that discourages the import of new and innovative medical devices.
4. *Fully consult with industry before conducting a Price-Volume Survey (PVS).* For years, BNHI has used PVS as leverage to cut prices on medical devices for cost control. After several price cuts, some devices have set world records for receiving the lowest reimbursement

price. Because of the severity of these price cuts, medical device companies in this market have been hard-pressed to maintain quality on their medical-care products while still earning a profit. The Committee urges BNHI to begin discussions with the device companies before a PVS is conducted, covering such subjects as the devices to be surveyed, the timeframe involved, and the guidelines to be applied in calculating the price adjustments. After completion of the survey, the results should be made available and appropriate forums provided for feedback on the price distribution and quantity of the surveyed devices, and on the proposed calculation of the price-cut percentage.

5. *Set fixed reimbursement rates for special medical devices.* Medical device companies tend to have higher operational costs than pharmaceutical companies because of the additional expenditures needed to train hospital personnel on how to operate the devices. In addition, the medical-device market is characterized by wide product diversity and short product cycles. Both factors cause the production cost of medical devices to stay high even after market launch. Further, the price of the products tends to increase as raw material prices rise. Following years of price cuts, however, some devices in Taiwan now receive the lowest reimbursement price in the world. Under the global budget mechanism, the reimbursement price for medical devices that fall under the "special device" category will undoubtedly tumble further because of the fluctuating point system by which BNHI assesses hospitals. These continued price cuts have pared the device companies' profit margins to unsustainable levels, but more importantly have discouraged them from introducing new and innovative products into the Taiwan market, depriving patients here of access to the best possible care.

Issue 4: Allow the import of medical devices manufactured in China by multinational enterprises.

More and more international companies are setting up manufacturing sites in China and exporting products from there to the rest of the world. Because the multinational companies apply the same level of quality control as in their home country, these products are certified for sale in the United States, the European Union, and other major markets. In many cases, however, Taiwan prohibits their import. The Committee hopes that the proposed Economic Cooperation Framework Agreement with China will include liberalization of the importation rules, but we understand that for medical devices, concerns about public health and the assurance of medical-care quality may continue to be a factor. We therefore urge the government to begin with the import from China of medical devices manufactured by multinational companies, especially those that have already proven to be of high standard by obtaining market approval in the United States and the European Union.