MEDICAL DEVICES

Health authorities around the world are facing the challenge of how to manage their regulatory regimes in the face of ever more rapid advancements in medical technology, along with a growing public demand for quality medical care, increasingly voiced through social media. Governments need to ensure that medical devices are effectively regulated for safety and efficacy, and that members of the public are adequately informed about their options as patients.

In Taiwan, the Food and Drug Administration (TFDA), recognizing that medical devices cannot be appropriately regulated under the existing Pharmaceutical Affairs Law, has begun work on drafting separate specific regulations for medical devices. The Committee appreciates TFDA's efforts in this regard, and looks forward to the completion of the draft regulations. A crucial element in this process must be the harmonization of the proposed regulations with international standards and practices, so that the review process for imported products can be expedited and more reliable post-market management achieved. Below are the Committee's specific recommendations.

Suggestion 1: Maximize participation and transparency in the regulatory process.

In line with the Second Generation National Health Insurance program's spirit of broad participation and information disclosure, the National Health Insurance Administration (NHIA) has gradually adopted various mechanisms aimed at involving more stakeholders in policy and case discussions. For example, medical-service providers now participate in the drug and medical device reimbursement review process, and patients have an opportunity to express their opinion on new devices during the review process. Medical device suppliers are able to provide feedback to the Special Materials Expert Group for consideration in the reimbursement review process and may attend meetings of the Expert Group to present their case for decisions on appeal. We commend these measures as positive developments. Fuller discussion from more perspectives will contribute to accelerating the introduction of new medical technologies.

As Taiwan gradually aligns with international trends on healthcare policy, such as the implementation of Tw-DRGs (Taiwan Diagnosis Related Groups), medical-device policy discussions are no longer limited to pricing and reimbursement issues, but extend to the application of various new medical-device technologies. Therefore, the industry should not be viewed simply as medical device suppliers, but rather as an important partner to assist in the introduction of new medical technology.

In the interest of promoting maximum participation and transparency in the policy-making process, the Committee

recommends the following:

1.1 Involve license holders of medical devices in the review process for new therapeutic procedures and procedure-covered devices. According to the reimbursement guidelines for medical devices, if there is no existing corresponding therapeutic procedure, the license owner of a newly licensed medical device may apply for NHI reimbursement only after a healthcare organization or medical association has applied for and received new-procedure approval. Self-pay codes for procedure-covered devices as defined by NHIA will be issued after consultation with the Taiwan Hospital Association or medical association regarding the proportion within the procedure to be allocated to the medical device. However, the license holders of new medical devices or procedure-covered devices are not involved in the therapeutic procedures review process. Their lack of information on the progress of the reimbursement process and the schedule for NHIA's issuance of self-pay codes increases their difficulty in planning product launches and gaining market access.

We recommend that NHIA consider medical device manufacturers as professional medical consultants and request the license holders of medical devices to participate in the process and share their opinions. NHIA should issue letters to healthcare organizations, medical associations, and the license holders of medical devices to inform them about the self-pay measures for therapeutic procedures and medical devices.

To encourage the development of new technology, we also suggest that healthcare organizations be allowed to accept self-payment in the following two situations:

(a) When the review process for a new therapeutic procedure application has been completed, and NHIA has requested additional documentation but has not given its final ruling.

(b) For procedure-covered devices as defined by NHIA, when consultation with the Taiwan Hospital Association or medical association regarding the proportion of the procedure to be allocated to the device has been underway for more than half a year, but a conclusion is still pending.

1.2 Increase the transparency of the reimbursement review process. We recommend that NHIA enhance the search function on its website for tracing the progress of application reviews for medical devices and therapeutic procedures in order to help manufacturers with their inventory planning and to assist clinicians and patients in developing appropriate plans for treatment.

1.3 Recognize fee-for-service special materials under DRGs in a lenient way and announce the principles and review process governing listed special materials. As a consequence of DRG implementation, members of the public are finding that their access to listed special materials is indirectly being limited. For medical devices with new functions, reimbursement by fee-for-service increasingly needs to be considered because either the quantity to be utilized is uncertain or the technology is not yet mature. In response to the implementation of phase 3 to 5 DRGs, some listed special materials have been made eligible to apply for fee-for-service. In the interest of transparency, we suggest that NHIA make public the assessment principles and process behind that determination for industry's reference. So as to encourage the listing of new medical devices in the NHI system, we also suggest increasing the proportion of devices eligible for fee-for-service under DRG and broadening the principles applied in determining that eligibility.

Suggestion 2: Establish a rational system for medical device reimbursement.

In Taiwan, the reimbursement pricing for medical device is based on functional categories. Devices with the same function are reimbursed at the same price. Variance in manufacturing costs and the length of time the device has been listed in the market are not taken into consideration. Besides the reimbursement price, pricing is also determined by price-volume agreements, the floating point value, price-volume surveys, and Tw-DRGs. The combination poses a definite challenge to the development of the medical device market, and affects manufacturers' willingness to introduce new products and technology in Taiwan due to the restrictions on price and volume under the multiple payment schemes.

The Committee would like to express its appreciation to NHIA for adopting various industry recommendations in recent years. These include the introduction of balance billing and self-pay management guidelines; elimination of unreasonable measurements in determining medical device reimbursement, such as reference countries' GDP; and continuous review of the price-volume survey mechanism. Such steps not only encourage manufacturers to steadily introduce new technology and devices, but gradually improve their willingness to supply products under the reimbursement scheme despite the limited NHI financial resources.

Reasonable pricing principles, a transparent and open review process, a predictable policy and business environment, and an appropriate free-market system are all important factors affecting medical device companies' decisions on introducing new products to a given market. To help establish a reasonable reimbursement system in Taiwan for medical devices, the committee recommends:

(a) Permit devices to remain in the self-pay market when the manufacturer does not accept the offered reimbursement price. With the adoption of Article 52-2 of the NHI Pharmaceutical Benefit Scheme, license holders now have

one chance to appeal an unsatisfactory price, and if the offered reimbursement price is still unacceptable, the self-pay code may be cancelled, basically freezing them out of the market.

There are numerous reasons why a manufacturer may feel unable to accept an offered reimbursement price. One is that the discount hospitals will request and future price cutting following a Price Volume Survey also have to be considered in deciding whether the price makes business sense. Another example is that sometimes the reimbursement is based on one of the other devices in the same functional group, which may not properly reflect the cost of other products in the group.

NHIA understandably wishes to increase the rate of adoption of reimbursement prices. But simply mandating that acceptance is out of place in a free-market economy. It also impact the entry of new-function devices into the market, to the disadvantage of patients seeking access to more technologically advanced treatments.

(b) ***Increase the frequency of the NHI committee's consideration of new balance billing categories to from the current two times a year to four.*** The balance billing payment program, by sharing the expenditure on a device between NHI and the public, makes more treatment options available for patients without increasing NHI's financial burden. For devices under balance billing, however, it is not sufficient to simply follow the assessment process and Expert Group review as with other new-function medical devices. Additional appraisal is needed by the NHI committee, which prolongs the waiting period for patients to access balance billing medical devices. Considering that only one or two new balance billing categories are created annually, we suggest increasing the frequency of NHI committee reviews of new balance billing categories to reduce the waiting time.

Suggestion 3: Streamline the medical device review system and make it more transparent and consistent.

3.1 ***Make products approved by U.S. FDA eligible for simplified review.*** The U.S. FDA review result serves as a supportive reference for international health authorities. We suggest that TFDA accept U.S. FDA approval as sufficient documentation to waive the requirements for submission of pre-clinical information and documents related to quality control and sterility, including specifications, test methods, test reports, certificates of analysis (CoA), etc. The result will be to speed up the registration process.

3.2 ***Allow the Certificate to Foreign Government (CFG)/ Certificate of Free Sales (CFS) to be submitted to TFDA before licensing.*** In November 2015, TFDA conducted an initial screening of its review mechanism. CFG/CFS was listed in the initial review as an essential item on the checklist. With this approach, many product submissions cannot be filed until the CFG/CFS is available. Given the rapid changes in modern science and technology, life cycles of medical devices are becoming shorter and shorter. Delayed submissions will prevent Taiwanese from benefiting from advanced medical devices and technology in time. We suggest permitting the CFG/CFS to be provided to TFDA not only at the time of submission, but also before licensing.

3.3 ***Accept the legal manufacturer as having responsibility for regulatory compliance.*** The Global Harmonization Task Force defined "manufacturer" as a natural or legal person with responsibility for the design and/ or manufacture of a medical device. This person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the device. Although it has become common for the physical production to be outsourced to a contract manufacturer, the design, performance quality, safety, and efficacy of the product – and the regulatory compliance – should remain the responsibility of the legal manufacturer. Accordingly, in the United States, European Union, and other major advanced countries, the legal manufacturer is the one to be regulated by the authorities. We recommend adoption in Taiwan of the concept of legal manufacturer to enhance harmonization with international regulations and accelerate the registration process for medical devices in Taiwan.

Suggestion 4: Allow information related to medical devices to be shared with the public.

With the introduction of balance billing and self-payment options for certain medical devices, patients need to be able to make informed decisions about the different devices available for use in their procedures. Healthcare-providing institutions and manufacturers should have the responsibility to educate the general public about product characteristics, applicable techniques, and relevant medical technology. If such information is openly shared, patients and their families are likely to have less concern about pending medical procedures and will be better able to make judgments regarding related payment issues. However, current regulations in Taiwan restrict the information that hospitals and medical device manufacturers (license owners) can disclose for some devices. Instead, people may turn to social media or web searching tools to obtain related information. Such information, if not authorized by the company or approved by the health authority, may be misleading or inaccurate.

In this age of globalization, we recommend that TFDA revise the pertinent regulations to permit the release of information aimed at educating the public, differentiating it

from advertising designed to promote sales. This change can help ensure that the general public obtains correct medical knowledge through proper channels in a timely and effective manner, thus improving the ability of patients and healthcare professionals to communicate in the interest of patients' welfare.