PHARMACEUTICAL

During 2015, the Taiwan government began preparations for a number of policy adjustments to bring about greater conformity with international practices and standards. As part of that exercise, the authorities also engaged widely in dialogue with stakeholders and took their recommendations into consideration.

The Pharmaceutical Committee applauds the progress that the Taiwan Food and Drug Administration (TFDA) has made in preparing regulations for patent linkage and data exclusivity. This legislation will aid Taiwan in establishing consistency with international practices, and help expedite Taiwan's participation in bilateral free trade agreements and multilateral agreements such as the Trans-Pacific Partnership (TPP) and the Regional Comprehensive Economic Partnership (RCEP). It will also create an environment that encourages and rewards investment in innovation. We hope the government will continue to work on developing increasingly robust intellectual property regulations.

Another new initiative is the launch by the National Health Insurance Administration (NHIA) of a patient commentary platform. The hope is to gather patient feedback for reference when new drugs are reviewed for the NHI reimbursement system. Though welcome, this step does not address the innovative pharmaceutical industry's concern over the pricing and reimbursement of new drugs. For example, a large gap still exists between the reimbursement prices in Taiwan and those of the 10 benchmark advanced countries. Moreover, the unpredictability of the new-drug pricing review timeline also presents problems. These continuous challenges could potentially delay patients' access to the new drugs they required.

In addition, with the three-year pilot run of the Drug Expenditure Target (DET) system now completed, the price-adjustment mechanism has become more predictable than in the past, and the recognition of single compound patents of combination formulation was a positive development to encourage innovation on dosage forms. Much room for improvement still remains, however, on the issues of transparency, predictability, and the reasonableness of pricing.

While both the TFDA and the NHIA have voiced support for expediting the introduction of new drugs into Taiwan, the hospitals' profit-based decision-making process and

their limits on the number of drug formulary items have consistently hindered the government's efforts to make more new drugs and treatments available to patients. Considering the importance of this issue, the Committee wholeheartedly recommends that the government continues to push for the complete implementation of separation of dispensing and prescribing.

As a key stakeholder in Taiwan's healthcare system, the research-based pharmaceutical industry looks forward to continued open dialogue with the government on these issues. We offer the recommendations below in the interest of helping to ensure that the people of Taiwan have access to innovative medicines enabling them to enjoy healthier lives.

Suggestion 1: Continue to strengthen IPR protection for innovative products, so as to ensure that the investment environment rewards innovation.

Creating an investment environment in Taiwan that encourages and rewards innovation will be essential for Taiwan's future participation in further bilateral and multilateral free trade agreements. It is also in line with the government's policy objective of encouraging Taiwanese biotech companies to develop new drugs for the international market. To achieve those goals, it is necessary to continue strengthening the protection of intellectual property rights. In the opinion of the Committee, the major gaps between Taiwan's current regulatory framework and that of high-standard trade agreements are:

(1) Lack of complete patent linkage mechanisms.
(2) Limited data exclusivity, which is confined to new components of new drugs.
(3) Lack of consistent application of patent-right protection across different government agencies.

The Committee recognizes the TFDA's progress in the past year in preparing the rulemaking framework for patent linkage and data exclusivity and engaging in inter-ministerial integration. We hope to see completion of these efforts and establishment of a complete support mechanism in the near future.

Also encouraging were the NHIA's efforts in 2015 to broaden the patent definition for Category 3A new drugs to include products with combination patents, as well as to increase the R-zone from 3% leeway to 5%. These are also positive developments toward facilitating the introduction of new drugs into Taiwan. However, the issues of hospitals' profit-making orientation and limitation on formulary items still significantly delay patient access to new drugs. The two percentage point increase in the R-zone in certain 3A products is not sufficient to help narrow the price gap, especially when the Ministry of Health and Welfare (MOHW) rewards the use of domestic new drugs through the hospital accreditation process and maintains a high-price policy for generic drugs. Government action is needed to secure more room for innovative new drugs that fulfill unmet clinical needs.

Recommendations:

1. ***Complete the legislative process for patent linkage and data exclusivity:***

a. Establish a simple, clear and workable regulatory system for patent linkage.
   (1) Follow U.S. practice by listing by patent number instead of patent claims to prevent TFDA from being embroiled in potential disputes over certification.
   (2) Rigorously implement IPR protection by releasing licenses and reimbursement prices to others only after the originator's patent has expired.
b. Extend data exclusivity coverage to new formulations and new methods of administration.
c. Achieve inter-ministerial alignment within the central government for consistent regulation for IPR protection.

2. ***Recognize all patents granted by the Taiwan government.*** Drugs that have effective patents recognized by the Taiwan Intellectual Property Office (not just compound patents but patents of all kinds, such as those covering use or indication, formulation, process, or salts, crystalline, polymorph, etc.) should be deemed as patented products.
3. ***Give special consideration to 3A items for price protection under DET.*** For category 3A new drugs, NHIA has agreed to broaden the patent definition to include combination patents and to increase the R zone from 3% to 5% within four years from 2015. The Committee urges NHIA to provide additional protection to certain types of products:
   a. Items under data exclusivity or within the surveillance period. As the objective of data exclusivity is to protect the data for new drugs, no generics should be on the market during this period. If new drugs face significant price risk due to the availability of generics, they may not be launched in Taiwan, depriving patients of access to the medication.
   b. Items with Risk Management Plans. Pharmaceutical companies make significant investments to implement RMP for drug-safety monitoring so as to reduce adverse effects on patients and help NHIA control spending.
   c. Mono-source compounds. Although the compound is off-patent, in the absence of generics only a single source may be available in the market. If these items suffer significant cuts and exit Taiwan, patient access will be impacted. Since no alternative source is available, they merit a 15% R zone.

Suggestion 2: Expedite the regulatory and reimbursement reviews of new drugs/ indications to ensure early patient access to innovative new drugs.

The adoption of innovative new drugs is one of the most

important factors in improving people's health. According to research data, the introduction of new drugs accounts for as much as 73% of the increase in life expectancy in developed countries. Another research study shows that 83% of the almost three-year increase in cancer patients' survival since 1980 can be attributed to new treatments.

Worryingly, however, the regulatory review in Taiwan of new drugs and new indications is now taking longer than before. In 2014, TFDA's review of new drugs (NCEs and new biologics) took 443 days (an increase of 35.5% from 2013), and for new indications it was 314 days (a 67.9% increase). In 2015, while the numbers slightly improved from 2014, there is still a substantial gap from the 2013 approval timelines. New-drug review took 421 days last year (28.7% longer than in 2013), while new indications took 312 days (66.8% longer). The Committee is deeply concerned that the delay in approvals will seriously impact patients' right to receive needed medications.

In addition, the Second Generation National Health Insurance program has now been in place for three years, but the issues surrounding new drug/indication reimbursement have worsened compared to the First Generation. Approval rates are lower, the review time is longer, and the prices approved continue to be much lower than the international median prices. On average, the reimbursement review for new drugs now takes 414 days, longer than under the First Generation. Worst of all is that the cancer drug review took 714 days, without any sign of improvement. Only 62% of cases received approval by the PBRS (Pharmaceutical Benefit & Reimbursement Scheme) meeting, while the effective reimbursement rate, accounting for companies that did not accept the offered price, was an even lower 42%. The Committee strongly urges NHIA/MOHW to expedite the review process and improve new drug pricing to help ensure that patients' medical needs are met.

Recommendations:

1. ***Improve and expedite the new drug regulatory review process.*** Both new drugs and new indications could be reviewed more effectively to speed up the timeline. Industry is pleased that TFDA has set a 2016 target for itself to review new drugs in 360 days and new indications in 180 days. We urge TFDA discuss means of improvement with industry and set mutually agreed-upon milestones to meet this timeline.
2. ***Increase the budget for new drugs/indications.*** To support the availability of future new drugs to meet patients' needs, industry urges MOHW/NHIA to devise new methodology, based on a reasonable estimation, predictability, and sustainability, to enable the budget to be increased for new drug/indication reimbursement within the Global Budget environment. Special attention should be given to breakthrough new drugs that provide exceptional treatment outcomes for unmet medical needs. A priority review pathway should be established for such drugs.
3. ***Provide more options for different new drugs by introducing appropriate MEAs or RSPs.*** We suggest that NHIA introduce more diversified MEAs (Managed Entry Agreements) and RSPs (Risk Sharing Programs) and provide more flexibility for companies to share the risk with government, especially for highly priced new drugs. The industry believes that such measures will help expedite the reimbursement process.
4. ***Establish a reasonable timeline for new drug/indication review and incorporate patients' opinions into the process.*** The Committee suggests that NHIA and industry representatives work together to set up reasonable timelines for new drug/indication review. As part of this process, all relevant documentation – including Health Technology Assessment (HTA) reports and minutes of the expert meetings and PBRS meetings – should be made available to key stakeholders. We also suggest that NHIA evaluate the possibility of inviting patient representatives to join the review and decision-making process.
5. ***Conduct periodic discussions with industry groups.*** We suggest that TFDA and NHIA hold periodic discussions with industry groups to further improve communication, exchange information, and build support for policy implementation.

Suggestion 3: Provide more funding to the healthcare system to enable it to meet future challenges.

The Committee would like to express our gratitude to NHIA for maintaining an open dialogue with the pharmaceutical industry over the past year and responding to the industry's suggestions by gradually reducing gaps in the price-adjustment mechanism. We believe that continuing communication between government and industry will facilitate the search for a transparent, predictable, and more reasonable mechanism for drug-price management. Taking DET as an example, the program, which has now completed its three-year pilot run, has brought better predictability than the Price-Volume Survey (PVS) approaches of the past, although the Committee believes the plan could be improved further to make the drug-price adjustment model more reasonable while still ensuring the sustainable operation of the NHI system.

We also acknowledge NHIA's dedicated efforts over the past year in reducing wastage in medical resources. The Pharma Cloud initiative to make patients' complete medical record accessible has achieved excellent results since its inception in 2013. In addition to enhancing patient medical safety, it has also effectively reduced waste from repeat prescriptions. In the future, full implementation of the HIS

Cloud will further enhance healthcare service efficiency and assure the availability of comprehensive and secure medical treatment for the public.

Besides waste reduction, Taiwan's healthcare system needs the input of more resources. In 2013, Taiwan's National Health Expenditure (NHE) amounted to NT$960 billion, equal to 6.63% of GDP. The NHE average in OECD countries during the same period was 9.3% of GDP. Up to 41.5% of the expenditure in Taiwan was through the private sector (mainly self-paid health expenditures such as NHI copayment, self-purchased medical supplies, etc.). The public sector component was only 58.5% (including NT$502.1 billion for NHI), far less than the 72% public-sector average in OECD countries. As the data shows, Taiwan not only has a relatively low overall health expenditure, but the contribution from the government sector is also unusually low.

Taiwan's healthcare system also faces the problem of budget shortages for new medical technology. Over the past three years, NHI set aside a budget of about NT$2 billion annually to introduce new clinic items, medicines, and medical devices. During the discussion at PBRS committee meetings on whether to add new items, however, committee members often expressed concern over the budget impact, resulting in a lower approval rate for new drugs. From 2009 to early 2016, Taiwan's reimbursement rate of new drugs was about 42%, far lower than the 54% average in OECD countries. This means that Taiwanese people may have to wait longer or self-pay to receive the benefits of new drugs.

The Committee urges the Taiwan government to continue to take effective measures to reduce medical resource waste as well as to take a more positive approach towards resource re-allocation. Our specific recommendations are as follows:

1. ***Increase healthcare expenditure and provide an adequate budget for new drugs.*** We urge the Taiwan government to refer to the experience of OECD countries and increase health expenditure to a reasonable level, especially by increasing spending in the public sector and planning an adequate budget for new drugs (including expenditures needed to cover policy changes, such as the transfer of HIV/AIDS costs to NHI starting in 2017). New drugs should be introduced in a timely fashion to maintain healthcare quality in line with global trends.
2. ***Develop a patient-centered policy to accelerate introduction of new drugs into hospitals.*** In addition to obtaining a license and NHI reimbursement from the government, new drugs must be listed in the drug formularies of the hospitals before physicians can prescribe the medication to patients. At present, hospitals generally apply a "one-in, one-out" principle at the time of a drug entry. That is, a new drug may be introduced only after an existing drug is removed. This practice affects patients' right to medication. Often only one or two items of a new drug that comes in several dosage forms can be introduced at a time, but the dosages or formulations that are available may not be what is most suitable for or most needed by the patient.

   Adding to the problem for imported products, the Taiwan government has listed "use of local-made new drugs" as one of the accreditation criteria for medical centers. We call on the government to adopt a fair and patient-centric approach that treats imported and domestic drugs equally, particularly regarding inclusion in hospital accreditation indicators.
3. ***Initiate payment system reform.*** With the accumulation of more than NT$200 billion in reserves, NHI is now in its most stable financial condition in many years. We recommend that the Taiwan government seize the opportunity to carry out payment-system reform by adjusting the medical-service payment standard to reflect actual clinical costs, and enabling hospitals to provide adequate compensation and benefit packages for healthcare professionals to ensure sufficient physician and nursing manpower. Through such reform, hospitals would no longer have to rely on drug-price margins to sustain their operations, restoring order to the pharmaceutical market.
4. ***Spearhead implementation of separation of dispensing from prescribing (SDP).*** The Committee has continually urged the Taiwan government to implement the separation of medical and dispensary practice. One of the keystones of SDP is to preserve doctors' autonomy to prescribe the drugs most suitable for treating the patient's condition. Another benefit is that community pharmacists are empowered to monitor prescriptions and help safeguard patients' use of drugs.

   At present, however, hospitals in Taiwan generally seek to "maximize" drug profits by taking advantage of formulary-listing restrictions and price competition. Even if a new drug has obtained a license and NHI reimbursement, the patient may still be unable to receive treatment with the drug due to the hospital's drug-management rules. The Committee believes that when a drug has been listed among the items receiving NHI payment coverage, the hospital must not limit the patient's right to medication due to profitability considerations.

   We urgently appeal to the Taiwan government to take action to implement SDP, ending hospitals' practice of deriving profits from drug prescriptions, and thus ensuring patients' right to the drugs they need.