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## Defense Industry: Ready for Take-off?

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# Bolstering Pharmacists' Professionalism

Upgrading efforts include new approaches to initial and continuing education, operational guidelines, and stricter laws on professional behavior.

BY SERAPHINA LIN

As Taiwan strengthens and modernizes its healthcare system, the role of the nation's community pharmacists will become increasingly important – bolstering patient care, helping to reduce the burden on major hospitals, and acting as a shield against the intrusion of counterfeit medications. Are Taiwan's pharmacists up to the challenge?

Although many experts would say they are not as yet, determined efforts are under way to upgrade the profession to eliminate past shortcomings. The primary focus, being undertaken by the Department of Health's Bureau of Pharmaceutical Affairs (BOPA) together with the country's colleges of pharmacy, is to revamp the way pharmacists are educated.

The first stage of reform took place in 2000. Previously, three different types of schools of varying quality were able to undertake pharmacy education. Graduates of either university-level institutions (of which the National Taiwan School of Pharmacy, founded in 1953, is the oldest and most prestigious) or junior colleges were eligible to sit for the Taiwan Pharmacy Licensure Examination or TPLEX (pronounced Tee-Plex). At the same time, graduates of pharmacy courses in vocational schools were qualified to



take the Assistant Pharmacists Exam. Although those who passed either exam were permitted to open a pharmacy and dispense drugs, only TPLEX-certified pharmacists were granted the legal right to dispense narcotics.

That wide disparity in the educational background of the person dispensing drugs was considered far from ideal, however. Since 2000, vocational pharmacy courses and the Assistant Pharmacists Exam have been terminated, pharmacy junior colleges have been upgraded to colleges, and all pharmacists are required to pass the TPLEX. Under a

“grandfathering” provision, those already possessing assistant-pharmacist certification have been allowed to continue practicing. But as many assistant pharmacists have gone back to school to become full-fledged pharmacists, and the youngest person still holding such certification is already 48 years old, BOPA predicts that this branch of the profession will soon be phased out by natural attrition.

Now the focus of attention has shifted to the content of pharmacy school curriculums. BOPA Director-general Liao Chi-chou notes that currently the emphasis of the curriculums is on “how to



synthesize new drugs, but this is not practical because the market is all about how to dispense drugs and how to take care of the patient." To address this issue, changes are being introduced to the TPLEX to put more stress on the practical skills needed in the profession. Starting in 2008, the proportion of the exam dealing with "dispensing pharmacy and pharmacotherapy" is being increased from 20% to one-third.

The Taiwan government and educational authorities have also been watching developments in the United States as possible models for Taiwan to follow. In 1992, the American Association of Colleges of Pharmacy changed the face of U.S. pharmacy education by implementing a six-year Doctor of Pharmacy program that emphasizes pharmaceutical care for patients. After a transition period, accreditation of the traditional Bachelor of Science degree in pharmacy was abolished in 2004, and newly licensed pharmacists are expected to hold the Pharm.D. degree.

Domestically, National Taiwan University is now proposing to establish the same type of six-year Doctor of Pharmacy program, starting with a pilot program in 2009 if the Ministry of Education gives its approval. If this initiative takes hold in Taiwan, it is seen as providing students not only with a better professional education but also with more employment opportunities internationally after graduation.

At the post-graduate level, a two-year internship program is being offered by most major medical centers and some community hospitals to provide pharmacy-school graduates with hands-on training, says Fe-Lin Lin Wu, a professor at the National Taiwan University School of Pharmacy. Completion of the program has been made a requirement for those wishing to open their own pharmacies, and this year the Department of Health also introduced an accreditation process for the postgraduate training programs for pharmacists offered by teaching hospitals. By monitoring and evaluating the curricula, the DOH is seeking to assure the quality of the training.

Due to the rapid advances in the pharmaceutical industry, the critical

importance of continuing education in the profession has also been recognized. BOPA Director Liao notes, for example, that "of the 1,000 drugs I studied in college, probably fewer than 20 are still on the market, while some 2,000 new drugs have been introduced." Given that situation, the Pharmacists Act was amended in March this year to require all practicing pharmacists to enroll in continuing education classes to assure their familiarity with newer pharmaceuticals. In fact, they must submit evidence of completion of the courses in order to renew their licenses.

These classes are offered by the Pharmacists Association, the Taiwan Society of Health-System Pharmacists, and university pharmacy departments. The emphasis is on understanding specific ailments and diseases, and then the medications available to treat them. BOPA hopes that eventually these courses will raise the professional knowledge of pharmacists sufficiently for them to be granted the right to dispense certain medications without a doctor's prescription. This practice would be similar to the proposed Behind-the-Counter (BTC) program currently being studied by the U.S. Food and Drug Administration to provide a third method of drug distribution aside from prescription basis and over-the-counter.

### Beyond the schools

An additional aspect of upgrading the profession is outreach programs to engage in public education and build a better relationship with prospective patients. The Community Education Program of Medication Use (CEPMU) established by BOPA, for example, is now in its fifth year. Under the program, volunteer pharmacists make presentations to interested civic groups to help raise people's awareness of how to use pharmaceuticals safely and effectively. Another program sends pharmacists out to small towns and villages at the end of each lunar New Year holiday. Residents are invited to bring out their medications for pharmacists to assess their continued efficacy. The pharmacists also advise people to throw out drugs with expired

prescriptions and seek to educate them on the importance on completing the full course of the prescription rather than stopping after a few days when they begin to feel better.

Another recent BOPA initiative has been to issue written standard operating procedures for pharmacists. The Bureau adopted this measure after discovering that some pharmacists were lax about such necessities as washing their mortar and pestle carefully before preparing a new batch of pills. Further, the revision of the Pharmacists Act this past March sought to crack down on improper practices by stiffening penalties for such offenses as leasing or lending licenses to others, engaging in criminal conduct (specifically including knowingly selling counterfeit or prohibited drugs), endorsing products with intent to mislead customers, undertaking grave or repeated acts of negligence, and violating professional ethics. Some of these problems were either not addressed in the original Act or were subject to only mild penalties.

Article 21-1 of the revised Pharmacists Act gives the DOH the authority to annul a pharmacist's license if he or she has engaged in illegal or fraudulent practice. That power, it is hoped, will help deter sales of counterfeit drugs and other illegitimate activities. Previously the maximum administrative penalty was a three-year suspension of the license – a step that was rarely imposed. The change may be particularly significant considering that the courts have consistently been reluctant to sentence IPR violators to severe judicial punishments.

[Editor's note: At a joint AmCham Pharmaceutical and IPR Committee meeting two years ago, a BOPA official said that the power to revoke pharmacists' licenses rested with the pharmacists association, a statement that was later repeated in *TOPICS*. It was learned in the course of reporting the current article that the association did not have that authority. As mentioned above, the government also did not have that power until this year].

According to BOPA, it has been making strides in countering sales of counterfeit pharmaceuticals, which have



been most prevalent in Taiwan in the drugstore channel. It has been working closely with Taiwan's Medical Product Anti-Counterfeiting Task Force, while also petitioning the World Health Organization for admittance into the International Medical Product Anti-Counterfeiting Task Force (IMPACT). BOPA says raids have been conducted each month in cooperation with prosecutors, local health authorities, and the police, resulting in approximately 300 indictments this year.

The accused have all been distributors rather than pharmacists, as the law requires proof of intent to commit a crime, and in the past pharmacists caught selling counterfeit goods have successfully claimed ignorance of the illicit nature of the products. (The pharmaceutical manufacturers contend that when pharmacies purchase goods outside of normal distribution channels at extremely low prices, the courts should take that as evidence of willful wrongdoing).

### Division of labor

A further problem for Taiwan's healthcare system is the heavy concentration of healthcare services within the major medical centers. A high proportion of patients with even minor ailments receive out-patient treatment at the hospitals, for example, after which they obtain their medication from the hospital's in-house pharmacy department. Aside from the temptation this creates for hospitals to prescribe drugs based on profitability rather than efficacy, it reduces the check-and-balance function that comes from involving an outside pharmacist.

In the late 1990s, a major step toward achieving the principle of Separation of Dispensing from Prescribing (SDP) was undertaken by mandating that all prescriptions had to be administered by certified pharmacists only. This led to the opening of more community pharmacies, but the full impact did not materialize because of the continuing dominant role of the hospital pharmacies. More than a decade later, the community pharmacies are still relying on the sale of vitamins, baby formula, diapers, and other



non-pharmaceutical products for the bulk of their revenue. An estimated 90% of all prescription drugs are still being dispensed by hospital pharmacies and private clinics, according to sources in the pharmaceutical distribution business.

There is a risk that these financial pressures could increase community pharmacies' vulnerability to counterfeit drug sales. Due to cost constraints, many pharmacies tend to buy pills in loose rather than individually packaged form, notes pharmacist Huang Yen-ming. That could make it easier for any unethical pharmacists to mix fake and genuine pills together, as has been found to have happened in many past counterfeit cases. Community pharmacies have also been known to buy re-sold drugs from hospitals or small distributors to try to benefit from bulk prices. Making purchases outside the normal distribution channel inevitably results in heightened risk of obtaining counterfeits.

Some community pharmacies have also engaged in illegal sales of prescription drugs without a prescription. Patients with chronic ailments, instead of returning to the hospital every three months to consult a doctor and refill the prescription as required under the National Health Insurance (NHI) system, may opt to have buy the medication without a prescription from an obliging neighborhood pharmacy. This poses health risks in cases where dosages should be altered. In more extreme cases, the customer is making purchases on the basis of self-diagnosis or the recommendations of a friend.

As AmCham's Pharmaceuticals Committee has argued repeatedly in the annual Taiwan White Paper, achieving complete separation of dispensing from prescribing would require readjustment of the NHI reimbursement system to eliminate the opportunity for hospitals to make large profits from discount drugs. That would remove the incentive for hospitals and clinics to run their own pharmacies, leading to the release of most prescriptions to community pharmacies.

In the meantime, BOPA Director Liao says adoption of a BTC program would also open more business to the community pharmacies and increase the responsibility of pharmacists within the healthcare system. In the United States, some of the types of drugs being considered for this program are those aimed at influenza infections, serious allergic reactions, and high cholesterol. Considering the heavy caseload of most physicians in Taiwan, which leaves them with only three minutes to spend per patient on the average, devolving a greater role to the pharmacist would bring distinct advantages.

While doctors are needed to make the diagnosis, well-trained pharmacists should be more knowledgeable than physicians about the suitability and efficacy of the various available drugs, particularly if the continuing education program works successfully, notes Liao. And the community pharmacists will have more time than the rushed doctors and hospital pharmacies to explain fully to the patient about dosages, side effects, and other crucial information.