

Extending the Deadline

Makers of diagnostic medical devices will be able to continue importing their products through December, even if registration procedures haven't been completed.

Taiwan's registration system for medical devices is currently being expanded to include, for the first time, the class of products known as in-vitro diagnostics (IVD). This category encompasses the analyzers and other lab equipment, reagent kits, and associated computer hardware and software used to conduct diagnostic tests in clinics and hospital labs. (The modifier "in-vitro" means that the tests take place outside the human body.)

According to the original schedule set last year by the Department of Health, the deadline for registration was set at June 20. But as that date approached, it was apparent that an enormous backlog of applications was developing - mainly due to insufficient manpower at the medical laboratory assigned by DOH to handle the project on an outsourced basis. Of the more than 4,000 IVD items marketed in Taiwan (95% of them imported), less than 10% of the applications had been dealt with by early June.

Concerned that a rigid adherence to the deadline would pose a healthcare problem by keeping many of these vital products off the market, a delegation from AmCham's Medical Devices Committee, together with a representative from the American Institute in Taiwan, paid a call on Health Minister Hou Sheng-mou. They explained that although DOH had earlier announced that products already in inventory could continue to be sold legally until the end of this year without a license, the special nature of IVD products reduced the significance of that option. Because of limits to their biological activity, these items normally have too short a shelf life to be kept in stock in large quantities.

In a display of pragmatism and flexibility, Hou immediately agreed to extend the deadline. As long as registration applications were received by June 20, companies may now continue to import products through December 20 whether or not the registration has been completed.

With a potential crisis averted, members of the industry are now concentrating on the details of their applications. It would be nice to report that all is now going smoothly, but in fact most companies are still finding the registration process to be an exercise in frustration. One typical problem arises because many medical devices, even those sold by U.S. companies, are manufactured in Europe. Given the differences in European and American classification systems, the product descriptions on the ISO certificates and other documentation provided by European qualifying institutions do not match the U.S. Food and Drug Administration terminology more familiar to Taiwan. The officers frequently ask for additional documentation to prove that the product scope is indeed the same; the companies scramble to find ways to satisfy them without going to the time and expense of requesting the European agency to provide additional information on every item.

If all goes well, this will all be sorted out by December 20. If not, will there be another extension?

- By Don Shapiro

Beef Again

Taiwan has re-imposed the ban on U.S. beef imports, but the move is unnecessary in light of the various measures to ensure that no health risk exists.

We thought we had seen the end of Taiwan's ban on imports of U.S. beef. We hadn't. In April, the government lifted a 15-month ban that had been imposed after a case of bovine spongiform encephalopathy (BSE), commonly known as mad-cow disease, was discovered in a U.S. herd. While that prohibition was in force, the American Institute in Taiwan (AIT) had called on Taiwan's regulatory authorities to lift the ban after conducting a thorough "science-based" approach to eliminate any doubts about the safety of consuming U.S. beef. Though the ban was lifted later than might have been wished for, and certain restrictions remained in force, AIT was satisfied that the Taiwanese authorities had handled the matter in a professional and credible manner.

But now, following a June announcement that a second case of mad-cow disease had been discovered in the United States, the ban is back. The U.S. beef industry and U.S. negotiators find themselves back at square one.

The Taiwan government's desire to protect public health is laudable, but reimposing the beef ban is unnecessary. As stated by AIT Director Douglas Paal, this "new" case of mad-cow disease is not in fact new, but rather is the result of the re-testing an old tissue sample from an animal that never entered the food chain or feed supply chain.

The animal was older than 30 months when slaughtered, meaning that Taiwan would not have allowed its import under existing regulations in any case. Further, the cow's birth predated the imposition of very stringent U.S. regulations governing the use of beef by-products in cattle feed - so the BSE was contracted under circumstances different from those that now exist in the United States. As Paal said, "there is no reason to compare this long-deceased cow with cattle that are now being used for U.S. beef exports."

In addition to the measures mentioned by Paal, new regulations to ensure the safety of U.S. beef introduced since the first case of mad-cow disease was discovered in the United States include a prohibition against using certain cattle products in human food, a set of stringent requirements on the handling of "non-ambulatory disabled cattle," and broad surveillance measures meant to detect any cases of BSE. These measures, which are intended to safeguard the health of both U.S. and international consumers of beef, should make clear that U.S. beef is a safe food product that poses no health risks.

U.S. beef is not only an important product in terms of bilateral trade, but it is also sought after and enjoyed by many Taiwanese consumers. In the absence of any health risk, there is no reason to deny that delicacy to domestic diners.

- By Lucien Crowder

TB - Not so Easy to Eradicate

The government has adopted an action plan designed to halve the annual number of new tuberculosis cases within a decade.

Decades after the public came to believe that tuberculosis had been virtually eliminated in Taiwan, media reports in recent months have made it appear that the disease has suddenly flared up again. In fact, "TB has never left us," says Wu Yi-chun, director of the TB division of Taiwan's Center for Disease Control. (CDC). "That the media didn't report on it didn't mean that it was eradicated. The reason you may not hear about it often is because patients don't want other people to know," considering it a stigma. She notes that the number of detected cases was around 12,000 to 13,000 annually for most of the past decade, though it has exceeded 15,000 cases a year for the past three years.

Taiwan has done rather well in controlling TB meningitis, which mainly attacks infants and small children. Currently 98% of all newborn babies receive vaccinations. As for TB in adults, Wu says the rise in cases in recent years may be more apparent than real. Previously only confirmed cases had to be reported, but now suspected cases must be as well.

Among the reasons why control of TB remains a very challenging task are the rise of AIDS (10% of AIDS patients are affected with TB), the presence of a large number of foreign workers and immigrants from less-developed countries, and the ever-increasing amount of travel between Taiwan and other parts of the world.

Public attention and government funding for TB control have increased since the CDC took over the task of TB control in 2001. Last year TB control received NT\$190 million (nearly US\$6 million) in public funding; this year the amount has risen to NT\$230 million (US\$7.2 million). An additional sum of at least NT\$1.8 billion (US\$56 million) is due to be appropriated to cover the healthcare costs of TB patients next year, relieving the Bureau of National Health Insurance of that burden.

A particular challenge with TB is that the disease is easily misdiagnosed. Some 15% of those initially identified as TB patients, in fact, later prove to be suffering from lung cancer. Starting this year, training programs are being provided to doctors and medical technicians at the hospitals to help improve the diagnosis procedure, including lab tests of patients' phlegm to supplement X-ray findings. The CDC has also arranged for nurses or paramedics to keep in close touch with patients through personal visits and phone calls to remind them to take their medication, and special efforts are being made to screen for TB in communities and institutions (such as prisons and old-age homes) with a high incidence of the disease. The goal is to halve the number of patients to 7,500 by 2015.

- By Lin Mei-chun