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Singapore - In Taiwan, biotech is finally booming, and new companies, service providers and manufacturing facilities are emerging to fill rapidly growing industry needs. BioSpectrum Asia recently spoke to **Dr Apo Huang, Secretary General, BioTaiwan** on the current growth in the Taiwanese biotech sector.

Q. The Ministry of Health and Welfare (MOHW) plays a key role in promoting pharmaceuticals and biotechnology in Taiwan, which has become particularly evident with many recent action plans. Any comments?

A. The TFDA (Taiwan FDA), part of the MOHW, is the agency responsible for pharmaceutical, medical device and biologics approval in Taiwan, and also covers food safety issues. Such issues have been in the spotlight in Taiwan in recent years. The MOHW also heads up Taiwan's world-renowned national health insurance program, under the National Health Insurance Administration (NHIA), providing high quality and affordable health care to all. Since 1998, TFDA has designated the CDE (Center of Drug Evaluation), a non-profit organization supported by MOHW for certain aspects of drug and medical device approval and the related regulatory matters. CDE's main role is to improve the quality and speed of clinical trials and drug approval processes. It also sets regulations for new therapeutic treatments such as cell therapy and ensures the transparency of review processes. CDE has played a very important role in Taiwan's biotech industry development with its accomplishment in setting priority review guidelines and accelerating drug and medical device approval processes. In the past five years, clinical trial applications have numbered around 250-300 (274 for 2016), with most cases being multinational, multicenter Phase II and III trials.

Q. What are the fundamental strengths of the biotech market in Taiwan and what challenges does it face?

A. Strengths include the following:

1. Strong and active government promotion of the industry, with high levels of direct and indirect investment, including sovereign funds such as the National Development Fund NDF), infrastructure development including the construction of a large number of science parks and clusters, policy development blueprints, etc.
2. Existing strengths in ICT, and growing capabilities in the newly emerging realms of IoT and AI all of which are transferable to medical device development, device-drug combinations, digital health/mobile health/e-health.
3. Utilizing Taiwan's National Health Insurance system which has compiled a huge medical database since its implementation in 1997, and which can be mined for important longitudinal studies for drug development.
4. Well placed to take a leading role in 'precision medicine', by combining capabilities in drug development, diagnostics, devices and utilizing Big Data analytics and methodology on the National Health Insurance Administration's massive medical database.
5. Taiwan has a Western business environment, strong IP protection, and enjoys a high degree of economic freedom. These are desirable qualities to developing such an internationally connected industry such as biotech.
6. Relatively easy access to capital, and strong public capital markets. Taiwan also has a vibrant and knowledgeable venture capital industry with long experience investing locally and overseas in biotech.
7. World-class clinical trials ecosystem; large network of medical centers (19 medical centers and 124 clinical trial hospitals), good reputation for adherence to protocols, and rapid patient recruitment. Taiwan has fast drug approval processes, particularly IND and has been a PIC/s member since 2013.
8. Entrepreneurial business culture, and fertile start up breeding ground. The subtropical climate is ideal for developing expertise in agri-biotech, tropic disease research, etc.

Q. Since the global financial crisis, Taiwan’s biotech capital markets grew by 520%. What do you think is the reason for this growth?

A. Yes, there has been huge growth in the value of listed life science companies since the financial crisis of 2008. The main reason being that after around 30 years of government-led developmental attention, the pieces have finally fallen into place, and the industry is beginning to blossom. Waves of new regulations are put into effect that allow better academic involvement in the private sector, and other benefits are now bearing fruit.

Since the new government took office in 2016, there has been a dedicated effort to build Taiwan up to become the center of biomedical R&D in the Asia-Pacific region. Also, the much-needed infrastructure has been built; toxicology facilities, clinical batch biologics manufacturing facilities, then later CMOs and locally-set up CROs.

Q. As Secretary General, can you highlight a few of the success stories of BioTaiwan over the past years?

A. BioTaiwan's growth is a reflection of the success of Taiwan biotech as a whole in recent years. Success stories of companies such as TaiGen Biotechnology, PharmaEngine and Panion & BF Biotech who have received new drug approvals in China, Japan or the US. Others such as PharmaEngine, TaiMed, Mycernax and SyneuRx International have drugs close to approval under fast track development or orphan drug designation. In biologics, Medigen Vaccine Biologics has a brand-new vaccine and biosimilars facility, while JHL Biotech and EirGenix and United Biopharma have new biologics CMO capacity and are also involved in an in-house biologics development. TaiMed and United Biopharma are working on exciting new drugs targeting HIV and are in Phase II or latter trials, while OBI Pharma and TheVax Genetics Vaccine have immuno-oncology drugs under development. There's growing biosimilars activity with United Biopharm, Mycenax, JHL Biotech, Fountain Biopharma and Tanvex Biopharma all with biosimilars pipelines.

Q. What is your outlook for the growth of Taiwan’s biotech and pharma sectors?

A. All sectors of the life science industry in Taiwan, including biotech, pharma, diagnostics and medical devices, are currently undergoing high levels of growth which we believe will continue for some time yet. With the government's growth goals to foster 20 new drugs and 80 high-value medical devices in global markets, and to create 10 flagship brands in health services all by 2025, with the target total revenue of NT$1 trillion (US$33 billion), and with industry confidence levels at an all-time high, the outlook is extremely positive.