
Taiwan Planned Major Promoting Program for Biotechnology and Pharmaceutical Industry

Taiwan Government Launched the "Biotechnology Action Plan"

The Taiwan Government has planned to boost the support and develop local industries across the following six major sectors: biotechnology, tourism, health care, green energy, innovative culture and post-modern agriculture. As the biotechnology industry has reached its maturity by the promulgation of "Biotech and New Pharmaceutical Development Act" in July, 2007, it will be the first to take the lead among the above sectors. Thus, the Executive Yuan has launched the Biotechnology Action Plan as the first project in building the leading industry sectors, to upgrade local industries and stimulate future economic growth.

Taiwan Government Planned to Promote the Biotechnology and Other newly Industries by Investing Two Hundred Billion

To expand every industrial scale, enhance industrial value, increase the value around the main industrial field, and to encourage the industrial development by government investments for creating the civil working opportunities to reach the goal of continuous economic development, the Executive Yuan Economic Establishment commission has expressed that, the government has selected six newly industrials including "Biotechnology", "Green Energy", "Refined Agriculture", "Tourism", "Medicare", and "Culture Originality" on November 19, 2009 to promote our national economic growth. The government will invest two hundred billion NT dollars to support the industrial development aggressively and to enhance the social investments from year 2009 to 2012. According to a Chung-Hua Institution for Economic Research report, the future growth rate will reach 8.16% after the evaluation, Hence, the future of the industries seems to be quite bright.

Currently, the government plans to put money into six newly industries through the existing ways for investment. For instance, firstly, in accordance with the "Act For The Development Of Biotech And New Pharmaceuticals Industry" article 5 provision 1 ",for the purpose of promoting the Biotech and New Pharmaceuticals Industry, a Biotech and New Pharmaceuticals Company may, for a period of five years from the time it is subject to corporate income tax, enjoy a reduction in its corporate income tax payable for up to thirty-five percent (35%) of the total funds invested in research and development ("R&D") and personnel training each year; provided, however, that if the R&D expenditure of a particular year exceeds the average R&D expenditure of the previous two years or if the personnel training expenditure of a particular year exceeds the average personnel training expenditure of the previous two years, fifty percent (50%) of the amount in excess of the average may be used to credit against the amount of corporate income tax payable. Secondly, according to same act of the article 6 provision 1 ", in order to encourage the establishment or expansion of Bio tech and New Pharmaceuticals Companies, a profit-seeking enterprise that (i) subscribes for the stock issued by a Biotech and New Pharmaceuticals Company at the time of the latter's establishment or subsequent expansion; and (ii) has been a registered shareholder of the Biotech and New Pharmaceuticals Company for a period of three (3) years or more, may, for a period of five years from the time it is subject to corporate income tax, enjoy a reduction in its corporate income tax payable for up to twenty percent (20%) of the total amount of price paid for the subscription of shares in such Biotech and New Pharmaceuticals Company; provided that such Biotech and New Pharmaceuticals Company has not applied for exemption from corporate income tax or shareholders investment credit based on the subscription price under other applicable laws and regulations. Thirdly, to promote the entire biotechnological industry development, the government has drafted the "Biotechnology Takeoff Package" for subsidizing the startup's social investment companies which can satisfy the conditions to invest in "Drug discovery", "Medical Device" or other related biotech industries up to 5 billion with the capital invest in domestic industry over 50%, , with operating experience of multinational biotech investment companies with capital over 150 million in related industrial fields, and with the working experiences of doctor accumulated up to 60 years.

Additionally, the refined agriculture industry field has not only discovered the gene selected products, but also combined the tourism with

farming business for new business model creation. According to the "Guidelines for Preferential Loans for the Upgrading of Tourism Enterprises" point 4 provision 1, the expenditure for spending on machine, instruments, land or repairing can be granted a preferential loan in accordance with the rule of point 6, and government will provide a subsidy of interest for loaning Tourism Enterprises with timely payments.

At last, Council for Economic Planning and Development also points out because most of technology industry has been impacted seriously by fluctuation of international prosperity due to conducting the export trade oriented strategy. Furthermore, the aspects of our export trade of technology industry have been impacted by the U.S. financial crisis and the economic decay in EU and US; and the industrial development seems to face the problem caused by over centralization in Taiwan. Hence, the current framework of domestic industry should be rearranged and to make it better by promoting the developmental project of six newly industries.

Taiwan Government Had Modifies Rules to Accelerate NDA Process and Facilitate Development of Clinical Studies in Taiwan

In July 2007, the "Biotech and New Pharmaceutical Development Act" modified many regulations related to pharmaceutical administration, taxes, and professionals in Taiwan. In addition, in order to facilitate the development of the biotechnology and pharmaceutical industries, the government has attempted to create a friendly environment for research and development by setting up appropriate regulations and application systems. These measures show that the Taiwanese government is keenly aware that these industries have huge potential value. To operate in coordination with the above Act and to better deal with the increasing productivity of pharmaceutical R&D programs in Taiwan, the Executive Yuan simplified the New Drug Application (NDA) process to facilitate the submission that required Certificate of Pharmaceutical Product (CPP) for drugs with new ingredients.

The current NDA process requires sponsors to submit documentation as specified by one of the following four options: (1) three CPPs from three of "ten medically-advanced countries," including Germany, the U.S., England, France, Japan, Switzerland, Canada, Australia, Belgium, and Sweden; (2) one CPP from the U.S., Japan, Canada, Australia, or England and one CPP from Germany, France, Switzerland, Sweden, or Belgium; (3) a Free Sale Certificate (FSC) from one of ten medically-advanced countries where the pharmaceuticals are originally produced and one CPP from one of the other nine countries; or (4) a CPP from the European Medicines Agency. Thus, the current NDA process requires sponsors to spend inordinate amounts of time and incur significant costs to acquire two or three FSCs or CPPs from ten medically-advanced countries in order to submit an NDA in Taiwan.

According to the new rules, sponsors will not have to submit above CPPs if (1) Phase I clinical studies have been conducted in Taiwan, and Phase III Pivotal Trial clinical studies have been simultaneously conducted both in Taiwan and in another country or (2) Phase II and Phase III Pivotal Trial clinical studies have been simultaneously conducted both in Taiwan and in another country. Besides, the required minimum numbers of patients were evaluated during each above phase. Therefore, sponsors who conduct clinical studies in Taiwan and in another country simultaneously could reduce their costs and shorten the NDA process in Taiwan.

The new rules aim to encourage international pharmaceutical companies to conduct clinical studies in Taiwan or to conduct such studies cooperatively with Taiwanese pharmaceutical companies. Such interactions will allow Taiwanese pharmaceutical companies to participate in development and implementation of international clinical studies in addition to benefiting from the shortened NDA process. Therefore, the R&D abilities and the internationalization of the Taiwanese pharmaceutical industry will be improved.

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