

## Taiwan Recent Regulatory Development- Promoting Biotech and New Pharmaceuticals Industry



Over the past twenty years, the Government has sought to cultivate the biopharmaceutical industry as one of the future major industry in Taiwan. Back in 1982, the Government has begun to regard biotechnology as a key technology in Technology Development Program, demonstrated that biotechnology is a vital technology in pursuit of future economic growth. Subsequently, the Government initiated national programs that incorporated biotechnology as a blueprint for future industrial development. In order to enhance our competitiveness and building an initial framework for the industry, The Executive Yuan has passed the Biotechnology Industry Promotion Plan. As the Government seeks to create future engines of growth by building an environment conducive for enterprise development, the Plan has been amended four times, and implemented measures focused on the following six areas: related law and regulations, R&D and applications, technology transfer and commercialization, personnel training, investment promotion and coordination, marketing information and marketing service.

In 2002, the Executive Yuan approved the Challenge 2008, a six-year national development plan, pointing out biotechnology industry as one of the Two Trillion, Twin Stars industries. The Government planned for future economic growth by benefiting through the attributes of the biotechnology: high-tech, high-reward and less pollution. Thus, since 1997 the Strategic Review Board (SRB) under the Executive Yuan Science and Technology Advisory Panel has taken action in coordinating government policies with industry comments to form a sound policy for the biotechnology industry.

Additionally, a well-established legal system for sufficient protection of intellectual property rights is the prerequisite for building the industry, as the Government recognized the significance through amending and executing related laws and regulations. By stipulating data exclusivity and experimental use exception in the Pharmaceutical Affair Act, tax benefits provided in Statute for Upgrading Industries , Incentives for Production and R&D of Rare Disease Medicine, Incentives for Medical Technology Research and Development, provide funding measures in the Guidance of Reviewing Programs for Promoting Biotechnology Investment.

Clearly, the government has great expectation for the industry through establishing a favorable environment by carrying out these policies and revising outdated regulations. Thus, the Legislative Yuan has passed the “Act for The Development of Biotechnology and New Pharmaceuticals Industry” in June, 2007, and immediately took effect in July. The relevant laws and regulations became effective as well, driving the industry in conducting researches on new drugs and manufacturing new products, increasing sales and expanding the industry to meet an international level.

For a biopharmaceutical industry that requires long-term investment and costly R&D, incentive measures is vital to the industry's survival before the product launches the market. Accordingly, this article will be introducing the recent important regulation that supports the biopharmaceutical industry in Taiwan, and analyzing the government's policies.

Biotechnology is increasingly gaining global attention for its potential in building future economic growth and generating significant profits. In an effort to support the biotechnology industry in Taiwan, the Government has made a step forward by enacting the “Act for the Development of Biotech and New Pharmaceutical Industry”.

The biopharmaceutical industry is characterized as high-risk and high-reward, strong government support and a well-developed legal system plays a vital role from its establishment throughout the long term development. Therefore, the Act was enacted tailor to the Biotech and New Pharmaceutical Industry, primarily focuses on tax benefits, R&D activities, personnel recruitment and investment funding, in support of start-up

companies and attracting a strong flow of funding worldwide.

To pave the way for promoting the biopharmaceutical industry and the Biotech and New Pharmaceutical Company, here the article will be introducing the incentive measures provided in the Act, and supporting development of the industry, demonstrating the efforts made by the Government to build a “Bio-tech Island”.

#### Reference

“Act for Development of Biotech and New Pharmaceutical Industry”, webpage of Law and Regulations Database of the Republic of China. 4 July, 2007. Ministry of Justice, Taiwan. 5 Nov. 2008 <http://law.moj.gov.tw/Eng/Fnews/FnewsContent.asp?msgid=3180&msgType=en&keyword=undefined>

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