# Analyzing the Framwork of the Regulation「Act For The Development of Biotech And New Pharmaceuticals Industry」in Taiwan

Taiwan Government passed The「Act for the Development of Biotech and New Pharmaceuticals Industry」for supporting the biopharmaceutical industry. The purpose of the Act is solely for biopharmaceutical industry, and building the leading economic force in Taiwan. To fulfill this goal, the Act has enacted regulations concerning funding, taxation and recruitment especially for the biopharmaceutical industry.

The Act has been seen as the recent important law in the arena of upgrading industry regulation on the island. It is also a rare case where single legislation took place for particular industry. After the Act came into force, the government has promulgated further regulations to supplement the Act, including Guidance for MOEA-Approved Biotech and New Pharmaceuticals Company Issuing Stock Certificate, Deductions on Investments in R&D and Personnel Training of Biotech and New Pharmaceuticals Company, Guidance for Deduction Applicable to Shareholders of Profit-Seeking Enterprises -Biotech and New Pharmaceuticals Company etc.

The following discussions are going to introduce the Act along with related incentive measures from an integrated standpoint.

1 、 Scope of Application

According to Article 3 of the Act,「Biotech and New Pharmaceuticals Industry」refers to the industry that deals in New Rugs and High-risk Medical devices used by human beings, animals, and plants;「Biotech and New Pharmaceuticals Company」refers to a company in the Biotech and New Pharmaceuticals Industry that is organized and incorporated in accordance with the Company Act and engages in the research, development, and manufacture of new drugs and high-risk medical devices. Thus, the Act applies to company that conducts research and manufacture product in new drug or high-risk medical devices for human and animal use. Furthermore, to become a Biotech and New Pharmaceuticals Company stipulated in the Act, the Company must receive letter of approval to establish as a Biotech and New Pharmaceuticals Company valid for five years. Consequently, company must submit application to the authority for approval by meeting the following requirements:

(1) Companies that conduct any R&D activities or clinical trials must receive permission, product registration, or proof of manufacture for such activities from a competent authority. However, for those conducted these activities outside the country will not apply.

(2) When applied for funding for the previous year or in the same year, the expense on R&D in the previous year exceeds 5% of the total net revenue within the same year; or the expenses exceeds 10% of the total capital of the company.

(3) Hired at least five R&D personnel majored in biotechnology. For New Drug and High-Risk Medical Device are confined in specific areas. New Drug provided in the Act refers to a drug that has a new ingredient, a new therapeutic effect or a new administration method as verified by the central competent authorities. And High-Risk Medical Device refers to a type of Class III medical devices implanted into human bodies as verified by the central competent authorities. Therefore, generic drug, raw materials, unimplanted medical device, and medical device are not qualified as type III, are all not within the scope of the Act and are not the subject matter the Act intends to reward.

2 、 Tax Benefits

Article 5, 6 and 7 provided in the Act has followed the footsteps of Article 6 and 8 stipulated of the Statute, amending the rules tailored to the biopharmaceutical industry, and provided tax benefits to various entities as「Biotech and New Pharmaceuticals Company」,「Investors of Biotech and New Pharmaceuticals Industry」,「Professionals and Technology Investors」.

(1) Biotech and New Pharmaceuticals Company

In an effort to advance the biopharmaceutical industry, alleviate financial burden of the companies and strengthen their R&D capacity. The Act has provided favorable incentive measures in the sector of R&D and personnel training. According to Article 5:「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 profit-seeking enterprise income tax payable, enjoy a reduction in its corporate income tax payable, for up to 35% of the total funds invested in research and development (R&D) and personnel training each year.」 Consequently, company could benefit through tax deduction and relieve from the stress of business operation.

Moreover, in supporting Biotech and New Pharmaceutical Company to proceed in R&D and personnel training activities, the Act has set out rewards for those participate in ongoing R&D and training activities. As Article 5 provided 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 pervious two years, 50% of the exceed amount in excess of the average may be used to credit against the amount of profit-seeking enterprise income tax payable.「However, the total amount of investment credited against by the payable corporate income tax in each year shall not exceed 50% of the amount of profit-seeking enterprise income tax payable by a Biotech and New Pharmaceuticals Company in a year, yet this restriction shall not apply to the amount to be offset in the last year of the aforementioned five-year period.

Lastly, Article 5 of the Act shall not apply to Biotech and New Pharmaceutical Company that set up headquarters or branches outside of Taiwan. Therefore, to be qualified for tax deduction on R&D and personnel training, the headquarters or branches of the company must be located in Taiwan.

(2) Investors of Biotech and New Pharmaceuticals Company

To raise funding, expand business development, and attract investor continuing making investments, Article 6 of the Act has stated that「In order to encourage the establishment or expansion of Biotech and New Pharmaceuticals Companies, a profit-seeking enterprise that subscribes for the stock issued by a Biotech and New Pharmaceuticals Company at the time of the latter's establishment or subsequent expansion; and has been a registered shareholder of the Biotech and New Pharmaceuticals Company for a period of 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 profit-seeking enterprise income tax payable for up to 20% of the total amount of the price paid for the subscription of shares in such Biotech and New Pharmaceuticals Company.」 Yet「If the afore-mentioned profit-seeking enterprise is a venture capital company (「VC」), such VC corporate shareholders may, for a period of five years from the fourth anniversary year of the date on which the VC becomes a registered shareholder of the subject Biotech and New Pharmaceuticals Company, enjoy a reduction in their profit-seeking enterprise income tax payable based on the total deductible amount enjoyed by the VC under Paragraph 1 hereof and the shareholders' respective shareholdings in the VC.」

The government enacted this regulation to encourage corporations and VC to invest in biotech and new pharmaceutical company, and thus provide corporate shareholders with 20% of profit-seeking enterprise income tax payable deduction, and provide VC corporate shareholders tax deduction that proportion to its shareholdings in the VC.

(3) Top Executives and Technology Investors

Top Executives refer to those with biotechnology background, and has experience in serving as officer of chief executive (CEO) or manager; Technology Investors refer to those acquire shares through exchange of technology. As biopharmaceutical industry possesses a unique business model that demands intensive technology, whether top executives and technology investors are willing to participate in a high risk business and satisfy the needs of industry becomes a critical issue. Consequently, Article 7 of the Act stated that「In order to encourage top executives and technology investors to participate in the operation of Biotech and New Pharmaceuticals Companies and R&D activities, and to share their achievements, new shares issued by a Biotech and New Pharmaceuticals Company to top executives and technology investors (in return of their knowledge and technology) shall be excluded from the amount of their consolidated income or corporate income of the then current year for taxation purposes; provided, however, that if the title to the aforesaid shares is transferred with or without consideration, or distributed as estate, the total purchase price or the market value of the shares at the time of transfer as a gift or distribution as estate shall be deemed income generated in that tax year and such income less the acquisition cost shall be reported in the relevant income tax return.」 Additionally,「For the title transfer of shares under the preceding paragraph, the Biotech and New Pharmaceuticals Company concerned shall file a report with the local tax authorities within thirty 30 days from the following day of the title transfer.」 Purpose of this regulation is to attract top executives and technology personnel for the company in long-term through defer taxation.

Moreover, the Biotech and New Pharmaceutical Company usually caught in a prolong period of losses, and has trouble financing through issuing new shares, as stipulated par value of each share cannot be less than NTD $10.Thus, in order to offer top executive and technology investors incentives and benefits under such circumstances, Article 8 has further provided that」 Biotech and New Pharmaceutical Companies may issue subscription warrants to its top executives and technology investors, provided that the proposal for the issuance of the aforesaid subscription warrants shall pass resolution adopted by a majority votes of directors attended by at least two-thirds (2/3) of all the directors of the company; and be approved by the competent authorities. Holders of the subscription warrants may subscribe a specific number of shares at the stipulated price. The amount of stipulated price shall not be subject to the minimum requirement, i.e. par value of the shares, as prescribed under Article 140 of the Company Act. Subscription of the shares by exercising the subscription warrant shall be subject to income tax in accordance with Article 7 hereof. if a Biotech and New Pharmaceutical Company issue new shares pursuant to Article 7 hereof, Article 267 of the Company Act shall not apply. The top executives and technology investors shall not transfer the subscription warrant acquired to pursuant to this Article.」

These three types of tax benefits are detailed incentive measures tailor to the biopharmaceutical industry. However, what is noteworthy is the start date of the benefits provided in the Act. Different from the Statue, the Act allows company to enjoy these benefits when it begins to generate profits, while the Statute provides company tax benefits once the authority approved its application in the current year. Thus, Biotech and New Pharmaceuticals Company enjoys tax benefits as the company starts to make profit. Such approach reflects the actual business operation of the industry, and resolves the issue of tax benefits provided in the Statue is inapplicable to the biopharmaceutical industry.

3 、 Technical Assistance and Capital Investment

Due to the R&D capacity and research personnel largely remains in the academic circle, in order to encourage these researchers to convert R&D efforts into commercial practice, the government intends to enhance the collaboration among industrial players, public institutions, and the research and academic sectors, to bolster the development of Biotech and New Pharmaceuticals Company. However, Article 13 of Civil Servants Service Act prohibits officials from engaging in business operation, the Act lifts the restriction on civil servants. According to Article 10 of the Act provided that 」For a newly established Biotech and New Pharmaceuticals Company, if the person providing a major technology is a research member of the government research organization, such person may, with the consent of the government research organization, acquired 10% or more of the shares in the Biotech and New Pharmaceuticals Company at the time of its establishment, and act as founder, director, or technical adviser thereof. In such case, Article 13 of the Civil Servants Service Act shall not apply. And the research organization and research member referred to thereof shall be defined and identified by the Executive Yuan, in consultation with the Examination Yuan.」 This regulation was enacted because of the Civil Servants Services Act provided that public officials are not allowed to be corporate shareholders. However, under certain regulations, civil servants are allowed to be corporate shareholders in the sector of agriculture, mining, transportation or publication, as value of the shares cannot exceed 10% of the total value of the company, and the civil servant does not served in the institution. In Taiwan, official and unofficial research institution encompasses most of the biotechnology R&D capacity and research personnel. If a researcher is working for a government research institution, he would be qualified as a public servant and shall be governed by the Civil Servants Service Act. As a result of such restriction, the Act has lifted the restriction and encouraged these researchers to infuse new technologies into the industry. At last, for advancing the development of the industry, Article 11 also provided that 」R&D personnel of the academic and research sectors may, subject to the consent of their employers, served as advisors or consultants for a Biotech and New Pharmaceuticals Company.」

4 、 Other Regulations

For introducing and transferring advanced technology in support of the biopharmaceutical industry, Article 9 stated that 「Organization formed with government funds to provide technical assistance shall provide appropriate technical assistance as may be necessary.」 Besides technical assistance, government streamlines the review process taken by various regulatory authorities, in order to achieve an improved product launch process result in faster time-to-market and time-to profit. As Article 12 provided that 「the review and approval of field test, clinical trials, product registration, and others, the central competent authorities shall establish an open and transparent procedure that unifies the review system.」

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