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Content

Title: Act For The Development Of Biotech And New Pharmaceuticals Industry

Date: 2017.01.18

Legislative: 1. 13 Articles published under Presidential Order Hua-Tsung-(I)-Yi-Tzu No. 09600083781, Jul. 4, 2007; and this Act shall come into force from the date of its promulgation till Dec. 31, 2021.

2. Article 3 amended, published under Presidential Order Hua-Tsung-I-Yi-Tzu No. 10600005941, Jan. 18, 2017.

Content: Article 1

This Act is enacted in order to promote the development of the biotech and new pharmaceuticals industry in the Republic of China so that it can bring about changes in the economic structure of the country.

Article 2

This Act shall govern the development of the biotech and new pharmaceuticals industry. Matters not provided for in this Act shall be governed by other relevant laws and regulations; provided, however, that where the provisions of such other laws are more favorable than those contained herein, the provisions of such other laws shall prevail.

Article 3

The following terms shall have the following meanings when used in this Act:

- 1. "Biotech and New Pharmaceuticals Industry" refers to the industry that deals in New Drugs, High-risk Medical Devices, and Emerging Biotech and Pharmaceutical Products used by human beings, animals and plants.
- 2. "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, High-risk Medical Devices, and Emerging Biotech and Pharmaceutical Products.
- 3. "New Drug" 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.
- 4. "High-risk Medical Device" refers to a type of Class III medical devices or a type of Class II medical devices requiring clinical trials for approval verified by the central competent authorities.
- 5. "Emerging Biotech and Pharmaceutical Product" refers to a biotech or pharmaceutical item designated by Executive Yuan as emerging with strategic development direction and announced after viewed by the competent authorities together with representatives from relevant authorities, academia, and research organizations called together by the competent authorities.

Article 4

The authority in charge of the implementation of this Act is the Ministry of Economic Affairs.

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 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.

The total amount of investment credited against the payable corporate income tax in each year under the preceding Paragraph shall not exceed fifty percent (50%) of the amount of corporate income tax payable by a Biotech and New Pharmaceuticals Company in a year; provided, however, that this restriction shall not apply to the amount to be offset in the last year of the aforesaid five-year period.

With respect to the investment tax credit referred to in the first Paragraph of this Article, the scope of its application, competent authority, deadline for filing applications, application procedures, enforcement period, tax credit rate and other relevant matters shall be prescribed by the Executive Yuan and be reviewed every two years for adjustment and modification as may be necessary.

Article 6

In order to encourage the establishment or expansion of Biotech 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.

If the afore-mentioned profit-seeking enterprise is a venture capital company ("VC"), such VC's corporate shareholders may, for a period of five years from the fourth anniversary of the date on which the VC becomes a registered shareholder of the subject Biotech and New Pharmaceuticals Company, enjoy a reduction in their corporate 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.

With respect to the investment tax credit referred to in Paragraph 1 of this Article and applicable to the shareholders of a Biotech and New Pharmaceuticals Company, the requirements, deadline for filing applications, application procedures, enforcement period, tax credit rate, calculation method for the deductible amount referred to in Paragraph 2 of this Article and other relevant matters shall be prescribed by the Executive Yuan.

Article 7

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. 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.

In the event that a technology investor is unable to provide documents proving the acquisition costs of the transferred shares when reporting its income under Paragraph 1 of this Article, thirty percent (30%) of the purchase price will be deemed the acquisition costs.

Article 8

Biotech and New Pharmaceuticals 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 (i) 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 (ii) be approved by the competent authorities.

Holders of the subscription warrant as prescribed in the preceding Paragraph may subscribe a specific number of shares at the stipulated price. The amount of the stipulated price shall not be subject to the minimum requirement, i.e. par value of the share, 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 Pharmaceuticals Company issues 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 pursuant to the first Paragraph of this Article.

Article 9

In order to introduce or transfer advanced biotech and new pharmaceuticals technologies,

organizations formed with government funds to provide technical assistance shall provide appropriate technical assistance as may be necessary.

Article 10

For a newly established Biotech and New Pharmaceuticals Company, if the person providing a major technology is a research member of a government research organization, such person may, with the consent of the government research organization, acquire ten percent (10%) or more of the shares in the Biotech and New Pharmaceuticals Company at the time of its establishment, and act as a founder, director, or technical advisor thereof. In such case, Article 13 of the Civil Servants Service Act shall not apply.

The research organization and research member as referred to in the preceding Paragraph shall be defined and identified by the Executive Yuan, in consultation with the Examination Yuan.

Article 11

In order to advance biotech and new pharmaceuticals technologies, to enhance the R&D collaboration among industrial players, public institutions, and the research and academic sectors, and to promote the Biotech and New Pharmaceuticals Industry, R&D personnel of the academic and

research sectors may, subject to the consent of their employers, act as R&D advisors or consultants for a Biotech and New Pharmaceuticals Company.

Article 12

In order to expedite the review and approval of new biotech and new pharmaceutical products, with respect to the various steps to be taken by each sector of the regulatory authorities before launching a new biotech and new pharmaceutical product, including the review and approval of field tests, clinical trials, product registration, and others, the central competent authorities shall prescribe an open and transparent procedure and unify the reviewing and approval system.

Article 13

This Act shall come into force from the date of its promulgation till December 31, 2021.

Data Source: Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System