The Biotech and New Pharmaceutical Development Act

As promoted by the announcement of the Biotech and New Pharmaceutical Development Act, pharmaceuticals are vigorous in R&D of new pharmaceutical products. It is estimated that 3 and 10 new biotech pharmaceutical products will be permitted to launch by the end of 2010 and 2015 respectively. The sales amount is estimated to reach NT$ 50 billion and 225 billion in 2010 and 2015 respectively to make significant contribution to the pharmaceutical industry.

Announced by the President and implemented on 4 July 2007, the Biotech and New Pharmaceutical Development Act is the first investment incentive bill introduced for an individual industry. Expiring in 2021, this is the only act that enables industries to enjoy tax incentives after the sunset of the "Statute for Upgrading Industries" at the end of 2009. The "Guidelines for Stock Warrant Issuance of Biotech and New Pharmaceuticals approved by the MOEA" was announced on 21 November 2007. Through times of negotiation, the "Regulations for the Applicability of Tax Offsets for Investment in Research and Development and Personnel Training by Biotech and New Pharmaceutical Companies" and "Regulations for the Applicability by Profit-Seeking Enterprises of Tax Offsets for Biotech and New Pharmaceutical Company Shareholders" were approved and announced on 29 February 2008.

To encourage the development of biotech and new pharmaceutical products, the "Regulations for the Applicability of Tax Offsets for Investment in Research and Development and Personnel Training by Biotech and New Pharmaceutical Companies" offers an exemption of 35 percent of the R&D and personnel training costs from business income taxes for a consecutive of five years. To encourage enterprises or venture capitals to invest in biotech and new pharmaceutical companies, institutional investors holding shares in biotech and new pharmaceutical companies for a consecutive of at least three years may offset 20% of the original cost of purchasing the shares from their business tax; institutional shareholders of venture capitals may offset business tax according to the ratio of investment.

The government promotes the development of the biotech industry through many projects such as: encouraging technology transfer of R&D achievement, developing unique pharmaceutical products, establishing pharmaceutical product export alliance, providing customized consultation to potential biotech companies, developing intelligent medical equipment industry, promoting international marketing of common brand name. We also actively attract foreign investors and produce results from the cooperation with international biotech pharmaceutical companies e.g. Crucell Company from the Netherlands has signed technology transfer agreement on the production of flu vaccine and agreement on strategic alliance with Admmune Corp.; TaiMed Biologics has signed the technology transfer agreement on TNX-355 for curing AIDS to conduct follow-up clinical tests; GlaxoSmithKline collaborated with the National Taiwan University Hospital to establish an R&D center for clinical test of vaccines; Novartis signed the 5-year project: "Novartis Pharmaceutical Research and Development Partnership Program" with the MOEA to invest in clinical tests, cultivation of pharmaceutical talents in order to assist the government to develop the pharmaceutical industry. All these cases show that our R&D capability in Biotech has gained recognition from the world. We hope the implementation of "Biotech and New

Pharmaceutical Development Act" can promote more collaboration opportunities in the future. We can further become an important link for the R&D, manufacture and operation center of international biotech group in the Asia Pacific region.

Influence of EuP on the Industry and Countermeasures of the IDB

According to Eurostat of the European Union (EU), the export production value of Chinese Taipei's energy-using products (the first-round 14 product lots) sold to Europe in 2007 is estimated to exceed NT$200 billion. Taking the value of OEM/ODM raw materials and parts to companies in the USA, Japan and other nations as well as the final products, the impact of the EuP Directive (Eco-design of Energy-using Products Directive, 2005/32/EC) on Chinese Taipei's industries may reach NT $600 billion per year.

Due to the importance of the EuP Directive and its enormous effect, the Industrial Development Bureau (IDB), Ministry of Economic Affairs (MOEA) initiated the "2008 International Environmental Regulation Compliance and Cleaner Production Promotion Project." The assistance for industries includes activities such as EuP Directive on-site consultation programs, compliance tools development, the analysis of the latest information, and related training and/or promotion. The on-site consultation, which is available for over 400 companies, contains a vertical supply chain format, a horizontal product specific format and a progress checking format.

The vertically integrated format will select 13 electrical device assembly factories or ODM plants to assist them and their key suppliers in implementing eco-design. In addition, assistance in preparing eco-profile reports will be provided to match the EuP Directive requirements for implementation measures and eco-design. The product specific format consultation will target producers of key EuP products/components, such as computers, PCBs and monitors. The progress checking format will focus on the EU published implementation measures (including drafts) to keenly check on the compliance of related-producers, and provide consultation/training/guidance services. At the present, this project is selecting companies through public procedures, companies are welcome to submit applications.

In order to integrate and enhance the strength of domestic capabilities in consultation under the EuP Directive, a specific training session for EuP consultants will be held to cultivate consultants and transfer experience in EuP consultation. Meanwhile, consultant organizations which are qualified for EuP consultation will be recruited for this project. In addition, this project will also promote the development of EuP tools, practicum seminars and technical manual editing to offer industries a total solution for complying with international directives and reinforcing industrial competitiveness. For more detailed information on these activities, please refer to the Cleaner Production Net (http://proj.moeaidb.gov.tw/cpnet/). Through the countermeasures of the IDB, we are sure to solve all possible EuP problems, establish consultation capacity, tools, information required for the industries to response to EuP in the following 3 years. Thus, our products exported to the EU are in compliance with EuP and reach a steady export growth.

Announced in 2005, the Eco-design of Energy-using Products, 2005/32/EC (EuP Directive), became effective on 11 August 2007. The directive gradually demands all energy-using products (except transportation tools) circulating in EU member countries to comply with the energy efficiency and environment performance

standards. It also prevents products that are incompliance with eco-design from entering the EU through the market mechanism. Due to the hierarchy of the global market structure, the seemingly local EuP Directive controls the global industries. In addition to self-created brand name products exported to the EU directly, all parts and components suppliers for international companies or international OEM factories are all regulated by the EuP Directive as their end products might be exported to the EU.

After the EuP Directive came into effect, EU members gradually announce domestic laws or update the development of relevant administrative policies. At the present, the substantial countermeasures in response to EuP of the EU members include the control of import of energy-using products and the establishment of relevant penalty, fines or even criminal liability. The harshest announced penalty at the present is that of Italy. The fine of single offense as regulated by the domestic laws in Italy reaches NT$ 6 million. The domestic law of the Ireland sets a maximum penalty of 3 years imprisonment. The EU expects to announce the Implementation Measures, IM, of the first round product lots. According to the draft of the 4th consultation and discussion of the external power supplies, the following standards shall be met after 6 months of implementation: 1. The energy consumption shall not exceed 0.5 watt when no loading; 2. when the output power(Po) is less than 1.0 watt, the average maximum energy consumption is 0.5 watt; when Po between 1.0~51.0 watt, the average energy consumption should be between 0.5~0.85 watt; when Po is greater than 51.0 watt, the average maximum energy consumption should be 0.85 watt. As a large EuP export economy including power supplies, in addition to providing assistance to information service and technical consultation, we also hope suppliers and relevant associations pay attention to relevant regulations and specification and actively take opportunities to discuss with the EU in order to express their opinions before the establishment of regulations for implementation.

From a global point of view, the EuP Directive has revealed a critical message that environmental protection capacity and green product development will be the core competitive value. The gate of the green market will welcome those are ready. The position of Chinese Taipei in the global integrated supply chain has driven government and industries to positively comply with this main green tendency.