Interview with Yeo-Pyo Yun, Commissioner, Korea Food & Drug Administration

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Please introduce the Korean Food and Drug Administration (KFDA) and its main health-related responsibilities within the Korean government…

The KFDA’s main duty is to cooperate and support with domestic and foreign governments, international organizations, research organizations, and related industries to develop safety management system based on the professional knowledge. The KFDA offers information on the production of superior quality medical supplies, confirming the safety and validity to adequately produce, supply, and use medical supplies, ensuring and maintaining quality standards. The KFDA has highly qualified human resources with a large percentage of the employees possessing PhDs, and has established a management system which connects the headquarters and 6 regional branches.

In a context of fast-changing regulations and Korea’s quick integration with the global economy, what are the major changes or transformations that the KFDA has undergone in recent times?

In order to give piece of mind to the citizens and support health-related businesses, the KFDA will serve, support, self-regulate and be responsive. The KFDA has been boldly removing formalities and administrative regulations unrelated to safety, strengthening administrative capacity, and closely cooperating with the industry to ensure safety and, as a new mission, to improve the competitiveness of the health industry. The KFDA will make efforts to continuously improve the

competitiveness of the health industry as well as maintaining safety. The mid to long term plan ‘Promise of Safety 2010“ has been established and promoted since the year 2006 for safety and healthier life of the people. Since the establishment and promotion of the total improvement counter-plan for the pharmaceutical areas last year, there have been positive acknowledgements and satisfactory responses by the public. 91% of the poll respondents agreed that the regulation reform promotion movement is supportive of the industry, 96% of the respondents agreed that the movement is supportive of the improvement of the industry, and 95% of the respondents agreed that the communication with the industry has been positive.

Also, by selecting the global standards for all steps from research to finished goods such as GLP, GCP, GMP, the safety and validity has been established as well as the management systems which harmonize with the international standards.

What programs and initiatives is the Korean FDA carrying out in order to make improvements in terms of efficiency and transparency?

In order to supply superior quality medical supplies, we have established a collective management system, which controls raw materials to finished products. Through the Drug Master File (DMF) system, we have blocked the inflow of the delinquent materials from the start, and managing global standards and internationally harmonized GMP system. Also, we are continuously examining the circulating products by collecting them and monitoring them to verify the quality.

In order to abolish unnecessary bureaucracy and promote transparency, we have established the safety management improvement counter-plan last year. Through this plan, steps and administrative regulations not related to safety have been improved last year. 7 major tasks and 27 important tasks will be selected for improvement.

The goal of the new government is to be a ‘serving government.’ Since the appointment as the new KFDA commissioner, we have upadated the ‘Customer Satisfactory Management’ by better serving, offering, and communicating with the pharmaceutical companies and the public. In order to promote this, the commissioner has been holding informal meetings regularly with the industry CEOs and personally visiting their sites to get a better understanding of the realities.

Moreover, in consideration of the KFDA transparency and accommodation to the public, Korea’s cutting-edge IT has been added to the electronic document circulating system (KiFDA) in order to manage all steps from petition approval, to examiner checking and online announcement of results.

How would you describe the KFDA’s level of activity and collaborations on the international arena?

The KFDA has organized the International Conference of Drug Regulatory Authority (ICDRA) with the WHO in Seoul with 81 participating countries and pharmaceutical control officials to harmonize regulations on safety, validity and quality improvement. We are also planning to establish an APEC Harmonization Center in June of this year to harmonize the regulations of medical and treatment supplies and act as the education as well as the hub center within the APEC area. Indeed, in July 2009 the APEC Harmonization Center will hold its first workshop and we are expecting the participation of many international organizations. Korea being a highly developed country in terms of IT, how would you describe the KFDA’s use of technology in order to increase its effectiveness? The KFDA which manages the final approval of medical products must understand and apply cutting-edge technology since these magnificent improvements in bio-technologies have been actively used in the medical development. As one of the key efforts by the KFDA, we are continuously executing references with the application of cutting-edge technology and new evaluation development research to check safety and validity of the products using IT, BT and NT. In order to further improve the safety estimations, we are strengthening the genomics research areas such as chemical genomics and toxicogenomics. In addition, we have decided to follow guidelines from the ICH and other developed countries for new medications developed using biotechnology, without domestic regulations.

As the clinical trial activity in South Korea continues to grow rapidly, what role is the KFDA playing in helping maintain this positive trend?

We are proud to say that the Korea’s clinical trials are the best in Asia and we are ready to be the hub for these activities. Such facts are evident by looking into the fast increase in multi-national clinical studies and evaluation results in the country. The KFDA will not settle for the current level but try continuously to make Korea the best place in the world for the clinical trials. In order to achieve such a plan, we have been expanding clinical infrastructure by expanding the regional clinical trial centers, preparing training programs for clinical trial personnel, and continuing research of the cutting-edge technologies in the clinical related areas with KoNECT (Korea National Enterprise for Clinical Trials) as the major organizer.

In order to further boost clinical trials in the country, the special centers have been expanded, approval steps and document requirements simplified, and regulations are being continuously adjusted. We are also planning to allow clinical trials for those seeking to do multinational “top 3” studies already approved by major countries upon simple presentation of a report, eliminating any additional KFDA requirements.

How would you rate the KFDA in terms of keeping up with international evolution of food and drug related regulations and guidelines?

It is very important for the growth of trade between countries to bring down technological barriers and to harmonize related regulations. The competition between countries in the global or Asian markets should be done equally within the boundaries of internationally harmonized regulations. Since it is the duty of the KFDA to supply safe and efficient medications as soon as possible within such an ever-changing international environment, most related regulations have been harmonized to the ICH standards. We are planning to propagate our expertise and contribute to the APEC countries using the harmonization experience by establishing the APEC Regulation Harmonization Center and cooperating with the ICH, GHTF, WHO and others to carry out education programs this year.

In your view, what would be the impact on the local pharmaceutical industry of the ratification of the Korea – USA Free Trade Agreement (FTA)?

The Korea-USA FTA, once obtaining congress approval, will increase the trade between the countries. With a lack of researchers due to the strengthening of the protection of the intellectual property and new delays in terms of the introduction of generic medicines on the market, small companies will see a decrease in their profits which have relied on the production of generics. However, we expect that this trade agreement will be an opportunity for those top companies with R&D and their own patents to grow into global players.

The strengthening of the intellectual property rules will make companies take the initiative to focus more on R&D for revolutionary new drugs, value-added drugs, biosimilars and other patent acquiring businesses. It will also expand the technological collaboration with the USA to strengthen the competitiveness of the domestic companies, focusing more on exports instead of targeting only the Korean market.

What are the main challenges and opportunities that you identify for the pharmaceutical industry and the KFDA in the coming years?

The most pressing issue for the pharmaceutical field is the FTA. The removal of the international barriers will give unlimited opportunities to some, but others will have to search for new business models. Secondly, the issue of safety will continuously expand. New technologies will bring up safety issues previously unknown. If the KFDA is not prepared scientifically to deal with these new safety issues and manage risks, it will create confusion in the society. We are planning to actively minimize and manage risks. Lastly, we are expecting to see the successful introduction of many

new and added-value drugs through R&D investments in Korea. Since drug research and development is a time consuming process, bold investments in the R&D are expected to profit in near future.

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