Chung Seung – Minister of Food and Drug Safety of South Korea



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Chung Seung, Minister of Food and Drug Safety, discusses the latest improvements to Korea's regulatory system and highlights vaccines, biosimilars and stem cell research as key components of the country's pharmaceutical sector.

What are the primary goals of the ministry today?

Since the Ministry of Food and Drug Safety (MFDS) has been promoted to a ministerial level in line with President Park's new administration in 2013, I have always tried to do my best to establish laws, regulations and systems fundamental to ensuring safe food and qualified drugs and healthy dietary life for Korean people. In particular, I have put the utmost efforts to promptly evaluate and approve medical products whether they are safe and qualified, so that a safe and sound environment focusing on consumers and patients can be made available to use medical products. The development of domestic pharmaceutical industry should be preceded in order to provide safe and efficient drugs to Korean people. We will actively support the development of generic drugs and R&D by offering information regarding patent conflict cases at home and abroad and patent approval cases on drugs.

Korea has the 14th biggest pharmaceutical market in the world; one of our objectives is to become the seventh largest. We can grow the market both internationally and domestically. To go abroad,

Korean pharmaceutical products must possess globally approved quality. The level of quality approval in Korea compared to Europe and the US for biologics is usually same; sometimes it is even better but this is not recognized worldwide. This must change. The Ministry is doing its best to publicize such information for those in the US, Europe or Japan. As such, I am frequently attending events hosted by the WHO, ICH, or APEC. We are actively participating in debates and discussions at the moderator level with such organizations.

What have been some of the most important achievements of the Ministry in recent years?

Since 2013, MFDS authorized two new drugs, and 19 incrementally modified drugs developed by domestic pharmaceutical companies.

In particular, MFDS authorized the first monoclonal antibody biosimilar in 2012, which is Remsima, the biosimilar product for Remicade, since then, MFDS has approved 3 more biosimilars.

In November 2013 MFDS was appointed to the chair of biosimilar working group in the International Pharmaceutical Regulators Forum (IPRF) due to the recognition of its experiences of biosimilar regulation and the continuous efforts for international harmonization by other global regulators.

In July 2014, Korea officially joined in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), which created a framework where international credit worthiness of domestic medical product’s quality can be elevated.

Furthermore, MFDS concluded MOUs with the Polish Office for Registration of Medical Products, Medical Devices and Biocidal Products, as well as the China Food and Drug Administration for further mutual cooperation. As a result of series of MFDS’ efforts, the Ecuadorian government officially announced a homologation that medical products approved by the MFDS are also automatically authorized in Ecuador, followed by Australia, Canada, EU and the US.

Until now, Korea has been producing generic drugs but nowadays our science is more developed to produce new drugs, particularly bio-based medicine. The Ministry has to leverage its position as a regulator in the government to get to international markets. To develop the pharmaceutical industry in Korea, the government and companies are providing training for human resources to meet the levels of tests as well as emphasizing R&D for the pharmaceutical industry.

What does the future of MFDS hold?

Korea has an increasingly ageing population growth and low rate of birth, as many developed countries are experiencing. The importance of bio-based medicines and products are being recognized by all people. Korea has two advantages in the areas of information and communications technology (ICT) and biotechnology (BT), in that the two are converging to lead to biologics development. I believe that the bio-pharmaceutical industry will be the key player which will drive Korean industrial development in the future.

By joining PIC/S, we will take full advantage of its membership: a qualification of participating in procurement priorities in the ASEAN pharmaceutical market; and an exemption of GMP inspection when participating in a competition of WHO's PQ project. We will organize a task-force team to provide export support according to the Homologation of the Ecuadorian government in order to provide a guidance of Ecuador's Customs Clearance and its regulations, as well as to seek measures for exportation in other Latin American counties. In addition, we will make further close cooperation with international organization such as WHO, ICH and APEC as well as major leading countries including EU, Japan and US. We will increase international creditworthiness of Korean medical products by continuously participating and promoting in AHC's activity and WHO Expert Committee on Biological Standardization. Besides, considering the characteristics of pharmaceutical industry as strictly regulated and intensive knowledge-based, ensuring qualified human resources is critical for the enhancement of industrial competitiveness. Therefore, we introduced the "Regulatory Affairs Certification System" (RA) to nurture experts in the industry.

Our goal is to nurture advanced-level experts who can meet requirements and standards on laws and scientific regulations from product development to post-surveillance including clinical trials, approval/license, and GMP. We will actively provide support to develop biological products such as stem cell therapy products by fully implementing a "Support Scheme for Global Biological Product" which aims at becoming one of the world's top seven powerhouses in the biological product field by 2017. We will rigorously support a commercialization of vaccines (being in the third phase of clinical trials), biosimilars, stem cell therapy products and gene therapy products. We will support domestic pharmaceutical companies advancing into the global vaccine market that grows annually by ten to 16 percent while we will make efforts to expand a self-sufficiency rate from currently 32 percent or nine items to 70 percent or 20 items in the domestic vaccine market (approximately nine percent growth) for the next six years.

The pharmaceutical industry represents a critical factor to the development of any country and plays a pivotal role in public health. Ultimately, I would like to say that our efforts must be a globally collaborative one in order to improve the health and wellbeing of individuals across the

globe.

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