

# CLINICAL AND EXPERIMENTAL VACCINE RESEARCH

Clin Exp Vaccine Res 2013;2:69-70  
<http://dx.doi.org/10.7774/cevr.2013.2.1.69>  
 pISSN 2287-3651 • eISSN 2287-366X

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Received: November 9, 2012

Revised: November 23, 2012

Accepted: November 27, 2012

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No potential conflict of interest relevant to this article was reported.

# Clinical trials for vaccine development in registry of Korea Food and Drug Administration

Based on the action plan "Ensuring a stable supply of National Immunization Program vaccines and sovereignty of biopharmaceutical products," Korea Food and Drug Administration (KFDA) has made efforts to develop vaccines in the context of self reliance and to protect public health. Along with the recognized infrastructures for clinical trials, clinical trials for vaccines have also gradually been conducted at multinational sites as well as at local sites. KFDA will support to expand six to eleven kinds of vaccines by 2017. In accordance with integrated regulatory system, KFDA has promoted clinical trials, established national lot release procedure, and strengthened good manufacturing practices inspection and post marketing surveillance. Against this backdrop, KFDA will support the vaccine development and promote excellent public health protection.

**Keywords:** Vaccine, Self-reliance, Clinical trials, Research and development

Vaccines, known as a heterogeneous class of anti-infective medicinal products containing antigenic substance, are only public health tool capable of preventing diseases to improve quality of life. Due to influenza pandemic in 2009 public is increasingly aware of the roles of vaccines and immunization. Korea Food and Drug Administration (KFDA) announced five action plans, one of which was "Ensuring a stable supply of National Immunization Program (NIP) vaccines and sovereignty of biopharmaceutical products" in 2010. Along with the action plan for vaccine sovereignty, the development of vaccines has been facilitated and encouraged from technical supports and investment for research and development (R & D) in cell culture vaccine and new vaccines for emerging diseases. KFDA has made efforts to develop vaccines in the context of self reliance and to protect public health since 2009. Fig. 1 shows the trend of approved clinical trials for vaccine development [1,2]. Clinical trials for vaccines have gradually been conducted at multinational sites as well as at local sites.

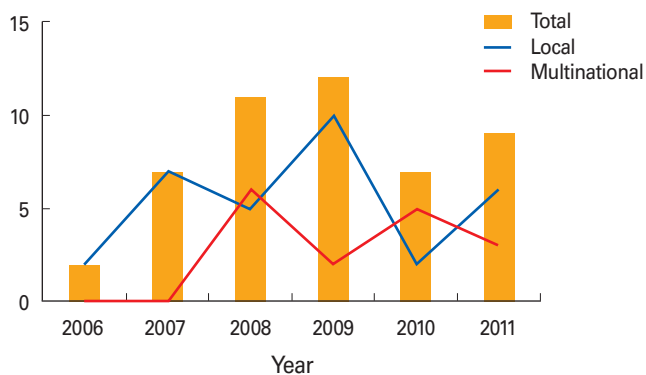
Total thirty-two of local clinical trials and sixteen of multinational clinical trials for vaccine development have been approved up to December 31, 2011 (Table 1) [1,2].

The clinical trial, which is the vital part of the approval process, has led to the expansion of vaccine industry. With release of December 2011 annual report by KFDA, vaccines are the major export products in field of pharmaceutical industry. Eight out of top ten export products are biopharmaceutical products such as vaccines, plasma derivatives, and recombinant products. Quinvaxam, a pentavalent vaccine against diphtheria, pertussis, tetanus, hepatitis B and *Hemophilus influenzae* type b, is the single



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**Fig. 1.** The numbers of approved clinical trials for vaccines in registry of Korea Food and Drug Administration from 2006 to 2011.

most exported item in 2011.

KFDA have reinvigorated clinical trials industry not only in the development of vaccines but with a wide range of diseases and conditions in Korea. The infrastructures for clinical trials have been established on a global scale. There were four hundred ninety of clinical trials approved and conducted in Seoul, 2011. Seoul was the city with the fourth greatest number of clinical trials that were conducted worldwide in 2011, which was followed by Berlin in German and Houston and New York in US.

The outcome has been driven from win-win strategy through R & D investment that pharmaceutical companies have seek to gain a competitive advantage and with stably secured investment consistent with the needs of the hospitals to perpetuate diverse and profound research. Ensuring a stable supply of NIP vaccines, KFDA has planned to expand from vaccines for eleven different types of diseases to them for twenty-two infectious diseases, which produced from domestic manufactures by 2017.

Only six out of twelve in the list of NIP could be produced in domestic manufactures in Korea. KFDA will support to expand six to eleven kinds of vaccines by 2017.

- NIP: Vaccines for varicella-zoster virus, typhoid fever, hepatitis B, etc., which administrated from community health centers and hospital settings and covered by national health insurance program
- Others: Vaccines for hepatitis A, pneumonia, etc., which not covered by national health insurance program

More clinical trials will be accompanied by the action plan, "Ensuring a stable supply of NIP vaccines." Based on excel-

**Table 1.** The numbers of approved clinical trials in biopharmaceutical products in registry of Korea Food and Drug Administration (up to December 31, 2011)

	Plasma derivatives	Vaccine	Antitoxin	Recombinant products	Cell therapy products
Local	4	32	14	92	81
Multinational	0	16	2	218	1
Total	4	48	16	310	82

lent clinical research infrastructure and medical researchers, pharmaceutical industry in Korea will be strengthened in the global pharmaceutical market. The paradigm shift towards integrated and preventive healthcare will be coordinated to invest R & D for vaccines and progressively to expand the market of vaccine industry.

KFDA has made efforts to provide technical support on construction and relocation of manufacture. KFDA will also improve any burdensome of regulatory obstacles over the whole life cycle of a product to expedite marketing through consultative groups with pharmaceutical cooperatives. KFDA enables domestic manufactures to expand overseas marketing opportunities by achieving the international competitiveness with human infrastructure and World Health Organization collaboration. KFDA has established lot release procedures of vaccines to assure the consistent quality of each manufactured lot. Therefore, it will strengthen the regulatory system as a part of the whole regulatory framework which includes marketing authorization, good manufacturing practices inspection, and post marketing surveillance, etc. Against this backdrop, KFDA will support the vaccine development and promote excellent public health protection by integrating regulatory systems.

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