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Vaccine industrialization in Korea: focus on major improvements and future direction

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When a disease-causing microorganism passes through the body, causes disease, and then recovery occurs from the disease, protective immunity is gained against the disease. A vaccine is a biological preparation containing artificially made protective immunity. Historically, through the use of these vaccines, humans were able to gain freedom from many kinds of dangerous infectious diseases; therefore, the significance of vaccines is beyond estimation. For example, in Korea, life threatening infectious diseases such as measles, rubella, Japanese encephalitis, polio, diphtheria, and tetanus have permanently disappeared. And, one of the most shameful fact that the Korean children showed the highest incidence of tuberculosis mortality rate in Asia has turned into the same situation of the developed countries.

Korea received the announcement of eradication of both polio and measles in the year 2000 for the first time in the Western Pacific region. However, these vaccines are mostly imported from overseas. Furthermore, the most basic vaccines, such as diphtheria, tetanus and pertussis (DTP) vaccine, polio vaccine, tetanus and diphtheria (Td), tetanus, diphtheria and acellular pertussis (Tdap) vaccine, bacillus Calmette-Guérin (BCG) vaccine, and Japanese encephalitis vaccine, which are implemented by the National Immunization Program (NIP), are all imported from overseas. Also, the inflow of newly developed vaccines from global companies occurs frequently, causing confusion among users because of vaccines with overlapping coverage.

As a result, the conditions involved in the development and manufacture of vaccines in Korea are still very elementary. However, new changes are starting to take place. A few pharmaceutical companies that have recognized the importance of the vaccine business have initiated an effort to develop and manufacture vaccines. These fetal movements in vaccine industrialization are very positive and desirable in terms of the development and manufacture of vaccines in Korea in the future. However, it is a pity that willing companies that possess insufficient technology make only impractical investments, and that some do not understand the significance of expense and time required for the development of vaccines. Also, the country itself recognizes vaccines simply as an industrial product and has interest only in the industrialization of vaccines without any regard to their implications as part of national defense, which is also very important

For vaccine industrialization, a thorough base must take precedence. There must be a manpower pool that has the ability to develop vaccines, comprising of experienced

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experts who can design vaccine manufacturing facilities and map out operations, a system that can carry out whole clinical trials, along with the development of domestic and foreign clinical research protocols and systems to carry these processes. In addition, marketing strategies for globalization of developed vaccines and a firm business foundation are needed. Furthermore, it should be recognized that vaccines are evidence-based medical products, the effects of which need to be recognized through inoculation into both healthy people and high-risk patients before use as a real vaccine. In these aspects, an investigator pool that can ultimately prove the safe use of developed vaccines must be established.

The development and industrialization of vaccines should only be followed after implementation of such protocols and systems.

In global vaccine manufacturing companies, thousands of researchers concentrate on the development of three to four new vaccines. It is evident that we cannot expect such conditions in Korea. Nevertheless, in the past, approximately ten researchers attempted to develop 10-12 vaccines. However, their efforts did not come to fruition. In our state, impractical vaccine development means failure and losing the will for vaccine industrialization. In these aspects, it is very important to decide which vaccine should be developed and manufactured for vaccine industrialization. Currently, development departments of many global companies say that they need to have discussions from the beginning of development regarding which vaccines to develop with the help of researchers and clinicians who are the final users. This is the only way to increase the rate of success in the development of vaccines, which requires significant time, investment, and effort. Also, even if a new vaccine is developed, many stages of clinical trials must be carried out before actual use, and the question of whether or not excessive expenses and time can be invested should be considered from the beginning. The reported expenses spent by global manufacturers on global clinical trials are hundreds of billions of won. We may find that hasty development of vaccines is very dangerous. In these aspects, the focus of domestic vaccine development should be on the development of vaccines that improve upon the problems of current vaccines, and, through this effort, we will be able to reduce the expense and time required for the development of global vaccines for better achievement with decreased clinical trial expenses. The development and industrialization of vaccines with goals targeting the aforementioned objectives can at last be called realistic domestic vaccine industrialization. I believe that it is very fortunate that some companies are currently attempting development through improvement of old vaccines. Vaccine industrialization has low practicality with only the effort and power of private enterprises involved. Many advanced countries support vaccine industrializing companies as a concept of a third defense industry for their people; for example, the development of smallpox vaccine and anthrax bacterium vaccine led to the possibility of bio-war. The governments in developed countries have developed and stored the smallpox vaccines and anthrax vaccines as stockpile vaccines for unpredictable bioterror or bio-war. This support also includes a

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NIP on inter-pandemic avian influenza vaccine as a strategy for eradication of infectious diseases, supporting the strategy for the maintenance of target vaccines, and revitalization of industrial and educational cooperation for technical support. Korea has a view on the distribution of vaccines at the same level as general drugs and industrial products, and considers vaccines as commercial products subject to international trade standards and Free Trade Association (FTA) standards. However, vaccines should be considered part of the defense industry and biological preparations made with the purpose of protecting the people, rather than considering them as simple chemicals. Therefore, vaccine industrialization should progress in a way that enables participation of the nation, organizations, and enterprises, and should be open to the public to gain people's interest. Moreover, the government should be more involved with the support of subsidies. In addition, there should be entireness in the selection of companies that have the will for vaccine industrialization. As such companies constitute an important position in the enterprise, they should execute vaccine development and industrialization with respect to human life and avoid misjudgement through assessment before impractical investment. Also, with regards to the business aspects of vaccine development, we should give thought to globalization of developed vaccines. Through the above contents, we desire and wish that the industrialization of basic vaccines by domestic companies be realized.

Jin Han Kang, MD
Department of Pediatrics, Seoul St.' Mary Hospital,
The Catholic University of Korea School of Medicine,
222 Banpo-daero, Seocho-gu, Seoul 137-701, Korea
Tel: +82-2-2258-6183, Fax: +82-2-537-4544
E-mail: kjhan@catholic.ac.kr

Sung-Ho Cha, MD
Department of Pediatrics, Kyung Hee University Hospital,
Kyung Hee University School of Medicine, 26 Kyunghee-daero, Dongdaemun-gu, Seoul 130-702, Korea
Tel: +82-2-958-8303, Fax: +82-2-958-8304
E-mail: sunghocha@khu.ac.kr