#### Executive Summary (영문)

### 2016 Horizon Scanning Service for Emerging Health Technologies in NECA H-SIGHT

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#### Background

As the healthcare industry is recently emerging as one of the key fields of national competitiveness, emerging health technologies and strengthened R&D infrastructure are often prioritized as part of the key objectives for investment in 2016.

While various ministries have continued to finance R&D projects in public health, there were some problems, including overlapping investment in the same research areas, and unsystematic and inconsistent R&D planning and management. Further, technologies newly introduced into the health system are frequently invalidated due to the errors in clinical trial design, lack of clinical evidence, or due to safety issues at the process of entering the healthcare system (in particular, at the stage of new Health Technology Assessment).

#### Objectives

In this study, we aim to establish an effective and intensive support system based on the problems of disconnected and inconsistent health technology support systems.

First, we provide information preemptively to a range of consumers, including health service providers, clinical researchers, industries, policy makers, licensor, and people through previously established Horizon Scanning. We will enhance the reliability and accuracy of the H-SIGHT activities through NECA H-SIGHT Toolkit reorganization and user satisfaction surveys.

Secondly, the objective of this study is to support the entry of domestically developed emerging health technologies into medical markets, and to contribute to the revitalization of the public health industry through collaboration with related institutions in Korea. A consulting support and collaboration system will be established in response to the request from the R&D management institutions and expanded to the management of promising health technologies.

## I. Horizon scanning of newly developed health technologies and Potential impact analysis

#### □ Methods

We investigated health technologies using the NECA H-SIGHT Toolkit at least once a year. In order to improve horizon scanning and feedback systems, a Delphi investigation was also conducted on stake-holders (experts) in various fields, the importance of each criterion for prioritization was evaluated. And standards were established for the update and re-assessment of reports that have already been published. Through a user satisfaction survey on publications related to horizon scanning, the overall satisfaction, continuing demand, and aspects to be improved were discussed, while various opinions were collected and considered.

In order to promote the global activities of NECA H-SIGHT, we participated EuroScan member and registrar activities. Using the H-SIGHT website developed in 2014, information on promising newly developed health technologies was also provided online to related academic societies, organizations, and individuals, and scanning and EuroScan-related activities were introduced.

#### Results

#### 1. Scanning of newly developed health technologies through scanning tools

A total of 260 health technologies were identified using the horizon scanning, and the last 4 technologies were selected. The features of selected technologies are as follows.

#### (1) Neurometabolic treatment for obesity "VBLOC®"

VBLOC® Therapy involves implantation of a device which is designed to work by intermittently sending electrical pulses to the vagus nerve. This is designed to reduce food intake and so cause weight loss. VBLOC®s is a simple and a non-invasive procedure. However, long-term follow-up research is still required on various side effects that can arise due to the blocking of the vagus nerve.

#### (2) "Leadless pacemaker" for treatment of cardiac arrhythmia

The leadless pacemaker, a small capsule-shaped pacemake, was developed to overcome the shortcomings of pacemakers that are implanted into the chest with leads. This technique is essential for patients who are contraindicated for procedures to implant permanent artificial pacemakers. The leadless pacemaker requires only a short procedure, the patients often only require a short recovery time without complications associated with invasive procedures. However, only single-chambered pacemakers is currently available and the development of dual-chambered shoud be done in the future.

#### (3) Hemophilia A drug "Elocta®"

Elocta® is a recombinant fusion protein produced inside human cells for the treatment of hemophilia. Due to its long half-life, it can be administered every 3-5 days when it is used for preventive substitution therapy (prophylaxis) in hemophilia A patients of all ages. In particular, since Elocta® is a long-acting injection, it was judged to improve patients' quality of life and doctors' convenience. However, due to its high cost, it can increase overall medical costs.

(4) A candidate drug for type 2 diabetes mellitus, "Efpeglenatide"

Efpeglenatide is a long-acting protein drug for type 2 diabetes that has improved convenience compared to existing drugs. Especially, it is developed by South Korea, and it can be supplied to the South Korean market at a relatively low price. However it is less competitive with existing drugs and the findings of phase 3 large-scale clinical trials are still pending publication, and its safety is still to be confirmed.

#### 2. Suggestions to improve horizon scanning and feedback systems

(1) Priority evaluation

With fifty experts, each criterion of priority evaluation was reviewed as following: clinical effects, disease burden, innovativeness, acceptability, economic effects, social ripple effects, and evidence. It is worthwhile to note that the importance of socially significant criteria, such as acceptability and social ripple effects, increased when compared to the results of the investigation conducted in 2014. The experts also suggested that a consideration of interests (conflict of interest assessment) for social groups is required.

(2) Standards for updating and re-evaluating published reports

In order to improve the feedback system, we performed periodic monitoring and archiving. And update and re-assessment standards have been set up to reflect changes in relevant clinical trials, publications and government policies. So an updated report (May 2016) was published on "extracorporeal shockwave treatment of cardiovascular diseases" the original report on this subject was published in 2014.

#### (3) Investigation of user satisfaction with published reports

To investigate user satisfaction, we surveyed approximately 300 e-mail users about the frequency, the types, their satisfaction, reasons, intention to use, and their preferred route of using publication materials.

In our survey, 58% of all respondents were satisfied with the current mailing service, and the most common reason was that they can easily access information through email. By type of publication, 88% received the newsletter, and 57% received the horizon scanning report. About 57% of the respondents were satisfied with the Newsletters, and the main reason was that the timing of publication was appropriate. Approximately 66% of respondents were satisfied with the Horizon Scanning Reports, and their favorite sections were 'Health technology assessment', which described clinical evidence, followed by 'Description for the health technology' and 'Impact on society according to experts'.

#### 3. EuroScan member activity

The EuroScan activities are mainly to participate in regular meetings, cooperate with various activities and share experiences of promising health technology activities internationally. In spring and fall of 2016, we attended regular meetings to share the recent activities of NECA H-SIGHT, and handled the issues about the transfer of the EuroScan secretariat, and cooperation with international councils.

#### 4. Information diffusion using a website and a homepage

Through the NECA H-SIGHT homepage, it provided a report on potential impact reports, activities and newsletters, and about 100 visitors per day were used. In order to improve the accessibility of information, we provided e-mail services for related organizations and we continued to spread abroad through the English version reports.

# II. Preparation of cooperation systems with national R&D organizations

#### 1. Cooperation with national R&D support organizations

Our agency promoted collaboration with government agencies as part of support system. Commercialization Promotion Agency for R&D Outcomes (COMPA), which cooperated with NECA, share information related to technology transfer and market trends, identified new joint research areas in horizon scanning for a full-cycle of health technologies and made a consulting group to support healthcare industry.

In cooperation with the Korea Health Industry Development Institute (KHIDI), we have proposed a preliminary consultation system to prepare for the evaluation of new health technologies in consideration of linkage with future new technology (NET).

The Korea Institute of Science and Technology Information (KISTI) signed a Memorandum of Understanding (MOU) in 2013. In 2016, in order to establish the Bio-Medical Technology (BMT) Intelligence being developed by KISTI, we have proposed BMT Intelligence application field and expectation effect from the perspective of the consumer in the health care field.

In this way, it is necessary to integrate diverse methodologies and convergence with other fields based on NECA H-SIGHT. We have sought to promote continuous collaboration with related organizations, intend to pursue efficiency of support and activation of market through concentration.

## 2. Cooperation with government departments: preparation of support for commercialization of promising health technologies

In order to establish a systematic and continuous system for expanding the market penetration of promising health technology, Task Force (TF) for improvement of health technology system was promoted in cooperation with various government departments. The Ministry of Welfare (MoHW) and related organizations gathered to form a consensus by discussing the issues

of health technology development, licensing and entry into the market. The Korea Health Industry Development Institute (KHIDI) and NECA have sought to promote strategies and cooperation for cutting-edge health technology. We have also arranged a support team with the Food and Drug Administration (FDA), the Health Insurance Evaluation and Assessment Service (HIRA) and NECA.

So far, the 'Medical Device Industry Comprehensive Support Center' has been established through cooperation with various related institutes. For practical use of promising health technology, our researchers have identified that it is needed for the role active counseling, support for clinical research design, potential impact and socio-economic value analysis. Therefore we will continue to support and cooperate for the effective management system of health technology in the whole period.

#### □ Conclusions

NECA has been exploring H-SIGHT since 2014, with the aim of discovering emerging health technology and preemptively providing information to policy makers, health service providers, the healthcare industry, and the public. This is to contribute to the efficiency of health insurance financing and the unnecessary reduction of the national health expenditure.

In 2016, we have made efforts to improve the efficiency of H-SIGHT, and will continue to perform continuous and intensive Horizon Scanning with the aim of discovering consumer-tailored emerging health technology.

Also, in order to establish a nationwide support system for the emerging health technology, we has sought to actively support the collaboration between relevant experts and government departments. In the future, if H-SIGHT activities are strengthened and the linkage system with related organizations is expanded to ensure stable operation of the system, we expect to maximize the efficiency of medical resources by providing whole-cycle support systems.

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#### Key words

Emerging health technology, Horizon scanning, Potential impact, Innovativeness