

Market Access for New Medical Technology in South Korea: A Case Study in Health Technology Assessment Policy Development and Implementation

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Abstract

In South Korea the new Health Technology Assessment (nHTA) program for medical technologies, including *in-vitro* diagnostics, was introduced in 2007. Although the nHTA program has made a positive and important contribution to the healthcare system, its introduction provoked unnecessary misunderstanding and conflict between stakeholders, due in large part to poor communication between parties, but also because the program had two distinct, and to a degree conflicting, objectives to fulfill: management of the national health insurance budget and promotion of the Korean health technology industry. The recent revisions of the nHTA program have led to a fairer, more objective and predictable decision-making process, which is very encouraging, however further improvements are required: in particular, a clear definition of what constitutes 'new medical technology' is essential; a more robust 'coverage with evidence development' process for promising technology is desirable; the 'Conditional nHTA Approval' program could be expanded to include reimbursement, and improved with guidelines for how the evidence generated will be utilized in subsequent nHTA assessment. These improvements to the nHTA program will ensure that the Korean community receives access to safe and effective innovations in technology, the health system budget is managed in a sustainable manner and the correct encouragement and guidance is given to the local medical technology industry, to help it compete in the global marketplace.

Introduction

South Korea has a universal coverage healthcare system funded through national health insurance, and medical technologies (medical devices) are paid for under fee-for-service or a Diagnosis-Related Group (DRG)-based scheme (though the latter is limited to only seven disease groups). Formal decisions about reimbursement coverage and price are made by the Ministry of Health and Welfare (MOHW) [1]. Previously, the safety and efficacy of new technologies were compared with existing technologies, and decisions about their reimbursement were based on the opinions of medical societies and clinical key opinion leaders. However, this practice lay open to criticism about the actual or potential risk of bias and lack of objectivity, and it became clear that a national system based on systematic and objective methods was necessary. As a result, the Medical Service Act was revised in 2006 and a new Health Technology Assessment (nHTA) program was presented for public consultation; new regulations enabling the nHTA program were enacted in April 2007 [2]. MOHW emphasized that the purpose of the nHTA program was to provide relevant information not only to health authorities but also to the general public, as a means of protecting the community's rights to health; however, a parallel objective was to promote development of the domestic medical device industry by encouraging scientifically proven new technologies, as set out in Article 53 of the Medical Service Act [3].

While the nHTA program for pharmaceutical products in South Korea is well known [4], the nHTA program applied to medical technologies (including *in-vitro* diagnostics) is less well understood. This paper highlights and discusses some of the key issues that impacted the development and implementation of this important policy measure.

nHTA Program Development

A new medical technology was defined as newly developed technology whose safety and efficacy the Minister of Health and

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Welfare determined needed to be assessed; however, established technology would also be subject to the nHTA program if there were changes to indication for use, or the target patient population, or related surgical procedure, etc. [2]. A clinical specialty-specific 'Sub-committee for nHTA', composed of 5 to 7 members selected from a pool of 548 stakeholders (healthcare professionals from specific specialties and other non-healthcare professionals) was to consider the evidence for safety, efficacy and effectiveness of a new technology and make recommendations; the final decision for nHTA approval was to be made by the 'Committee for nHTA', comprised of 20 members, mainly healthcare professionals. Upon establishment of these two committees, MOHW commissioned the Health Insurance Review and Assessment Service (HIRA) to initiate the nHTA program, which formally began in June 2007. In June 2010, MOHW transferred the nHTA commission to the National Evidence-based Healthcare Collaborating Agency (NECA), which was also tasked with determining within 90 days of receipt of an application whether the technology was eligible for nHTA assessment (Table 1).

The nHTA program for medical technologies was very different from that applied to pharmaceutical products: the underpinning legislation was different, as were the government organizations responsible, and the assessment objectives and methodologies (Table 2). Also, the key tool in nHTA was systematic review of the safety and efficacy literature [5], and a formal economic evaluation was not required (unlike for pharmaceutical products) (Table 2).

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Year	Milestone event ¹
July 15 th 2003	MOHW requested HIRA to develop an nHTA program
July 19 th 2003	HIRA organized nHTA task force
October 27 th 2006	MOHW promulgated a revised Medical Service Act to introduce nHTA program
April 27 th 2007	MOHW enacted the nHTA program
April 28 th 2007	MOHW implemented the nHTA program
June 15 th 2007	MOHW commissioned HIRA to undertake the nHTA program
December 3 rd 2007	HIRA launched the 'Center for nHTA'
June 15 th 2010	The 'Center for nHTA' at HIRA was transferred to NECA
November 4 th 2013	MOHW implemented a pilot 'Parallel Review' program (locally known as 'nHTA One-Stop Service'); 10 medical technologies were selected for the pilot program which ran from November 2013 to July 2014
July 30 th 2014	MOHW officially implemented the 'Parallel Review' program
September 23 rd 2014	MOHW implemented a 'Conditional Approval of nHTA' program ²
September 21 st 2015	MOHW implemented 'Temporary deferment of nHTA' program
February 22 nd 2016	MOHW implemented the pilot program of 'Single application for combining regulatory and nHTA submissions'

Table 1: Chronology of the nHTA program [3, 18-21].

¹HIRA : Health Insurance Review and Assessment Service; MOHW : Ministry of Health and Welfare; NECA : National Evidence-based Healthcare Collaborating Agency

²The 'Conditional Approval of nHTA' program was originally entitled the 'Temporary Approval of nHTA' program.

Implementation Issues

Under the new arrangements, new medical technologies approved by the Ministry of Food and Drug Safety (MFDS, formerly the Korea Food and Drug Administration, KFDA) but without subsequent nHTA approval were prevented from accessing the market [1] - a barrier

	Medical technologies	Pharmaceuticals products
Legislation	Medical Service Act	National Health Insurance Act
Organization in charge	NECA (supervised by MOHW) ¹	HIRA (supervised by MOHW)
Assessment aspect	Safety and efficacy (effectiveness)	Economic evaluation
Assessment tool ²	Systematic review	CMA; ICER value, determined using CEA or CUA; BIA

Table 2: Differences between the nHTA programs for medical technologies and pharmaceutical products.

¹The 'Center for nHTA' at HIRA was responsible for the nHTA program since its introduction in June 2007, but NECA took over responsibility in June 2010.

²BIA : Budget Impact Analysis; CEA : Cost-Effectiveness Analysis; CMA : Cost-Minimization Analysis; CUA : Cost-Utility Analysis; ICER : Incremental Cost-Effectiveness Ratio

unique to Korea amongst 'universal coverage' healthcare systems which use HTA for reimbursement and market access decision-making. As a result, the number of nHTA applications soared (Table 3), but about half of the applications were determined to be 'existing technologies' or 'early-stage technologies' and therefore ineligible for the program, or were withdrawn by the applicant (Table 3).

Stakeholders, particularly domestic manufacturers of medical devices and *in-vitro* diagnostic technologies, vigorously protested the nHTA program blocking access to the market for their licensed products. The key issues raised were (i) the redundancy of assessment of safety and efficacy post-regulatory approval, (ii) market access of licensed medical technologies being delayed for 12 months during the nHTA process, and (iii) the policy principle that MFDS-approved medical technologies were unable to enter the market without prior nHTA approval [7]. To discuss the issues raised, the Division of Healthcare Resource Policy at MOHW (which supervised the nHTA program) invited representatives from MFDS, NECA, medical societies and the medical technology industry to a stakeholder meeting

Year	Number of applications	Applications pending ¹	Applications ineligible for nHTA program ²	Applications subjected to nHTA program				
				Eligible applications	Reviews in progress	Completed reviews		
						Passed	Failed ³	Decision pending
2007	55	0	30	25	0	15	8	2
2008	359	0	193	166	0	132	29	5
2009	142	0	90	52	0	38	12	2
2010	135	0	70	65	0	44	17	4
2011	194	1	89	104	0	72	30	2
2012	238	0	111	127	2	95	24	6
2013	286	1	138	147	31	100	10	6
2014	39	28	3	8	8	0	0	0
Total	1,448	30	724	694	41	496	130	27

Table 3: nHTA program statistics: applications submitted between May 1, 2007 and March 31, 2014 [6].

¹Applications pending for unspecified reasons.

²Existing technologies, early-stage technologies or withdrawn applications are not subject to the nHTA program.

³Early-stage health technologies routinely fail to obtain nHTA approval and are denied market access.

in September 2012. At the meeting industry made the point that it usually took 6 to 24 months for regulatory approval by MFDS, 12 months for nHTA approval, and a further 12 to 24 months for reimbursement and price approval, 2.5 to 5 years in total, an unnecessarily long and protracted timeframe for market access of a new technology [7]. Significantly, at the meeting MFDS and MOHW/NECA clashed, with the former strongly asserting that the nHTA policy and program in effect blocked the entry to market of products it had already approved for sale, a situation without precedent globally.

To try and resolve the controversial issues raised at the September 2012 stakeholder meeting, MOHW assembled a special task force, composed of representatives from MFDS, HIRA, NECA, medical societies, domestic and foreign medical technology manufacturers, to establish detailed principles about candidate technologies and assessment criteria for the nHTA program, and to improve the overall efficiency, predictability and integrity of the program. The task force held its first (of five) meeting in August 2013, and as a result of its recommendations the nHTA program was revised, as outlined below [8].

Revision of nHTA Program

Operational procedures

MOHW revised the nHTA program as follows [9]:

- (i) the operational fairness and objectivity of the 'Committee for nHTA' was enhanced;
- (ii) criteria were established for which technologies were subject to the nHTA program; criteria were also established for waiving the requirement for nHTA assessment in cases where the new technology would have little impact on public health and safety;
- (iii) provision was made for expert opinion to be presented directly to the 'Sub-committee for nHTA' on behalf of an applicant.

'Parallel Review'

To address the long delay in the overall review and decision-making process, MOHW convened a working group from three agencies, MFDS, NECA and HIRA, to consult widely and develop proposals for a 'Parallel Review' program, involving simultaneous review of both the regulatory submission (assessed by MFDS) and the nHTA application (assessed by NECA). The feedback from a pilot program run by NECA between November 2013 and July 2014 was positive therefore, with the expectation of shortening market access lead-times to within a 3 to 12 months range, MOHW implemented a 'Parallel Review' program from July 2014 [10].

'Conditional nHTA Approval'

MOHW also introduced a new regulation, 'Conditional nHTA Approval', to allow market access for certain new technologies without sufficient evidence for their safety and efficacy, but on condition that the evidence required for nHTA approval is generated [11]. Technologies which are approved by MFDS for indications with few alternative treatments, or for the diagnosis or treatment of intractable diseases, and which are also at low risk of abuse, are eligible. Only MOHW-approved medical institutions can participate in the program, and they must satisfy specific clinical research-related requirements, including an Institutional Review Board (for oversight of the evidence-gathering project), establishment of a medical safety and accident prevention system, be subject to field audit, and submit

to NECA an interim and final report, etc. The program is similar in principle to 'coverage with evidence development', 'only in research', etc., schemes established elsewhere [12-15], but differs in that while research costs are funded by MOHW, procedure fees, including the cost of the medical technology, are paid for by patients out-of-pocket [15].

'Temporary deferment of nHTA'

In the special case of a new medical technology which gained regulatory approval based on review of the clinical research literature, MOHW allowed the nHTA review to be deferred for 12 months and access to market temporarily permitted on condition that (i) comparative clinical research evidence against existing technologies is collected and submitted for regulatory approval (however, if the indication is for rare disease, or there are no alternative technologies available, this requirement is waived), and (ii) the technology is used only for the indications licensed by MFDS. During the deferment period, the costs of both medical procedure and technology usage are borne by the patient [16-18].

'Combined regulatory and nHTA submission'

In addition to the reforms outlined above, in response to a recommendation from the Regulatory Reform Committee (the body overseeing government-wide regulatory activities [19]) that the nHTA process be streamlined and expedited, in February 2016 MOHW and MFDS piloted use of a single application for both regulatory and nHTA assessment processes. The program is aimed at technologies which need clinical evidence for licensing purposes and also clarification of their clinical indication; it is similar to the 'Parallel Review' program outlined above, except that MFDS receives the submission and, after successful review, issues a license along with nHTA approval. The licensing and nHTA reviews progress in parallel, and MOHW/NECA and MFDS collaborate much more closely (MFDS officials may attend the 'Committee for nHTA' to discuss issues related to licensing, and MOHW or NECA officers may attend MFDS meetings to discuss the design of clinical trials and other evidentiary requirements from an nHTA perspective) [20].

Discussion

The development and implementation of nHTA as a critical part of healthcare policy in South Korea is a good case study of the importance of clarity of objectives and good communication between stakeholders. The program has been valuable in support of systematic decision-making about reimbursement, and between its introduction in 2007 and 2015, 1,942 medical technologies were reviewed and about 34% (660 products) were approved [15]. However, initially there was a high level of mistrust and resentment against it, particularly amongst domestic medical technology manufacturers and healthcare providers, who believed that the program was not only redundant but also disadvantaged them, in that foreign suppliers were much better positioned to develop the evidence required by nHTA through having acquired access in other markets. The reason for this dissatisfaction was due in part to a profound misunderstanding of the nHTA program and the government's administrative objectives. This in turn was mainly caused by a lack of in-depth discussion amongst, and communication between, all the stakeholders involved at the very beginning of the program's development. Discussions about key elements, such as why the program was introduced, anticipated conflict of interests (for instance, regulatory approval versus nHTA approval), the potential opportunity for clinical evidence

development, etc., only took place six years after the program was in place. In addition, the nHTA program's initial design and operation created further significant confusion - for instance, the criteria for selecting technologies for review were unclear.

A key complicating factor was that MOHW did not establish a clear and consistent policy objective about the nHTA program at the outset, and failed to secure the understanding of stakeholders. Initially, introduction of the nHTA program began as part of the previous government's plans to improve the domestic healthcare service industry, and it had somewhat different objectives to the HTA programs adopted in other countries. The Korean government had been making efforts to enhance the domestic healthcare service industry's global competitiveness for over a decade. In 2005 the MOHW officially launched a task force for the development of the healthcare industry, including the medical technology industry, aiming to improve the autonomy and efficiency of the healthcare system, and also to support development of medical technology, in order to provide both quality medical services domestically and to enhance Korea's global competitiveness technologically [21-23]. Of the five recommendations for improvement made by the task force, introduction of the nHTA program was selected and MOHW announced that the initiative was to facilitate the early introduction of new medical technology into the Korean market, and also to facilitate achievement of national industrial development goals (in terms of growth in the development of new health technologies - drugs, medical devices, etc.) [24-27]. Because the MOHW conflated two separate policy issues, health service delivery and industrial development, in its communication of an important initiative, deep confusion and suspicion about the purpose of the nHTA program quickly developed amongst stakeholders.

A further complication was that MOHW had a third objective in introducing the nHTA program: reducing out-of-pocket payments, in other words, non-reimbursement coverage. Although South Korea has a popular universal healthcare system financed by national health insurance, the general public has been resistant to supporting it with increased premiums, and successive governments have been reluctant to press the issue, and as a result public healthcare spending in South Korea remains well below the OECD average (55.9% vs. 72.7% in 2013), and most new medical technologies entering the market are paid for by patients out-of-pocket [28]. The MOHW had long wanted to both correct the distorted healthcare market driven by out-of-pocket payments and to increase public spending, through efficient use of the national healthcare insurance budget and selectively allowing market access to only clinically proven new medical technologies. Since previous efforts had failed (with the community apparently willing to continue paying out-of-pocket), introduction of the nHTA program presented another mechanism and opportunity.

Another complication in the development and implementation of the nHTA program was the conflicts of interest between the various governmental ministries involved, which had different cultures and, importantly, different objectives and influence within government; for instance, MFDS's initial view that nHTA was redundant and undermined its licensing decisions resonated with the Ministry of Strategy and Finance and the other ministerial stakeholders whose clear objectives were to develop the domestic medical device industry and whose views were influential within government [29].

Although the government's reforms of the nHTA program were welcomed, unfortunately, some aspects have not operated as well as

anticipated. For instance, the 'Conditional nHTA Approval' program has not been taken up, indicating it does not fulfill stakeholders' needs. Apart from the program being funded by out-of-pocket payments, part of the problem is that there is little clarity about how the evidence generated will be used for subsequent nHTA approval. The 'Temporary deferment of nHTA' initiative, intended to facilitate temporary market access of new technologies, is also unappealing because of the demand for comparative clinical research evidence, something relatively uncommon in the medical device and diagnostics sector - reflected in only one application to the program as of the end of April 2016. The 'Combined regulatory and nHTA submission' initiative obliges manufacturers to submit a single application package covering both regulatory and nHTA evidentiary documents to MFDS, at first glance an advantageous arrangement - however, it also poses significant risk to manufacturers, in that failure to achieve a positive nHTA review results in regulatory approval also being withheld, and therefore the access to market completely blocked.

Finally, and crucially, a clear definition of what constitutes 'new medical technology' still needs to be established. Currently, a technology is classified as 'new' and must undergo the nHTA program if it cannot be included within an established procedure code (i.e., reimbursed under the umbrella fee-for-service payment scheme). However, the issue is that this classification mechanism is too broad; over the last seven years, 653 technologies were determined to be 'new' and subjected to nHTA approval (Table 3), a large number, which not only raised suspicions about biased assessment, but also clearly does not help to make the nHTA program operationally efficient. A narrower and clearer definition of 'new technology', more reflective of the wide variety of modern device and diagnostic products available, is urgently required. Finally responding to this urgent need, MOHW recently announced it would redefine the technologies to be subjected to nHTA and reduce the number of products reviewed by 44% for *in-vitro* diagnostics and by 38% for medical devices [18].

Conclusions

The nHTA program in South Korea is a good case study of the complexity of healthcare policy development and implementation - of the interplay of community engagement, professional and commercial interests, government imperatives, intra-governmental conflict, and of the crucial importance of clarity of objectives and good communication. Although the nHTA program has made a positive and important contribution to the healthcare system in South Korea, its poorly managed introduction provoked unnecessary misunderstanding and conflict. The actions of the MOHW were central in this respect - but it too was compromised by having two distinct, and to a degree conflicting, objectives to fulfill: management of the national health insurance budget (by funding only safe and efficacious new technology in a sustainable manner) and promotion of the Korean health technology industry (by encouraging development and utilization of new health technologies).

The recent revisions to the nHTA program have led to a fairer, more objective and predictable decision-making process, which is very encouraging. However further improvements are required: a clear definition of 'new medical technology' is essential; a more robust 'coverage with evidence development' process for promising technology is desirable; the 'Conditional nHTA Approval' program could be expanded to include reimbursement, and improved with guidelines for how the evidence generated is to be utilized in the

nHTA program. These improvements to the nHTA program will ensure that the Korean community receives access to safe and effective innovations in technology, the health system budget is managed in a sustainable manner, and the correct encouragement and guidance is given to the local medical technology industry, to help it compete in the global marketplace, where in many cases HTA is the key tool for funding decisions.

Competing Interests

The authors declare that they have no competing interests.

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