Pharmacoeconomic Evaluation Exemption and Deferral in Korea – Impact on Patient Access?

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BACKGROUND

Since the introduction of the positive listing system (PLS) in Korea, only new drugs that have proven cost-effectiveness may be listed. However, due to conservative pharmacoeconomic evaluation (PE), the number of non-reimbursed drugs increased, and to address this problem, a pathway that enables exemption from PE was introduced in 2015[1]. However, concerns have been raised regarding the bypassing of cost-effectiveness review, which is central to PLS, as well as the increased listing of high-cost cancer drugs through this pathway. The government recently announced the results of an external study conducted to improve the PE exemption (PEE) system[2].

OBJECTIVE

The objective is to compare the PEE pathway criteria proposed by the external study the current criteria and to analyze whether new drugs listed under the current criteria would still qualify under the proposed criteria. This will help assess the impact of the proposed reform on patient accessibility.

METHOD

We analyzed whether the 33 drugs that were listed through the PEE pathway from 2015 (when the PEE pathway was first introduced) until September 2023 would still qualify for PEE under the newly proposed criteria. Using the cost-effectiveness exemption as the outcome indicator, we examine in which domains the requirements were strengthened or relaxed compared to the current criteria.

RESULT

The PEE pathway, introduced in 2015, has undergone several changes, as shown in <Table 1>. From the perspective of the pharmaceutical industry, these changes involve restricting the system rather than expanding it. The main changes include mandatory application of expenditure cap and making small patient population (fewer than 200 patients) a prerequisite.

According to the results of this study, the PEE system has improved patient access to new drugs for serious diseases, however, it has shown limitations in that it focuses more on whether its eligibility criteria are met rather than on whether reimbursement is appropriate. Therefore, the recommendation is to change the system to allow for a deferral, rather than an exemption, from economic evaluations, with strengthened criteria as follows: 1) regardless of gene type and treatment stage, the small patient number criterion should be “fewer than 200 patients based on the disease as a whole,” 2) drugs with no prior economic evaluation conducted overseas, and 3) substantial and significant clinical improvement.

Table 1. Reform of PEE pathway

Major Reforms	Details
Pathway Introduction ('15.5)	• Application of expenditure cap only when there is small number of patients
Reimbursement scope expansion and expenditure cap ('16)	• When the expanded scope satisfies criteria for PEE: possible through negotiation • When the expanded scope fails to satisfy criteria for PE exemption: possible through negotiation upon proving cost-effectiveness • Expenditure cap: mandatory
Inclusion of PEE as RSA scheme and expansion of scope ('20)	• Application in combination with other RSA schemes made possible • Follow-on drugs subject to identical scheme applied to predecessor PE exemption drug • Essential drugs that meet certain conditions
Expansion of scope and changes to application method ('22)	• Rare disease and cancer drugs demonstrating improvement in quality of life for pediatric patients are also eligible for PE exemption. • Addition of external reference country • Small number of patients mandatory

Among the 33 products, 23 (69.7%) were anti-cancer drugs, 6 (18.2%) were orphan drugs, and 4 (12.1%) were others. Under the current criteria, most drugs listed through PEE were based on the criteria that there be no alternatives or drugs with equivalent therapeutic position and that it be difficult to produce evidence. However, under the revised criteria, none of the 33 products meet the requirements for PEE. The most difficult criteria to satisfy are the requirement for lack of PE abroad and the less than 200 patient requirement for a single disease.

CONCLUSION

After the introduction of the PLS, many innovative new drugs experienced delays or failures in reimbursement listing due to conservative economic evaluations. To improve patient access to new drugs for life-threatening severe diseases, the government introduced the PEE pathway. This led to reimbursement of cancer drugs and rare disease treatments that had not been listed for a long time, and it shortened the evaluation period for many innovative new drugs. However, there have been ongoing criticisms that this approach contradicts the PLS principle of listing only cost-effective drugs. In response, the government released the results of a study on potential improvements to the PEE. If the proposed reforms are introduced, there is high likelihood that the system will lose its original purpose as a relief measure and instead serve only as a regulatory barrier.

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References

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