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EFPIA Views on a Yearly NHI Drug Price Revision

The Council on Economic and Fiscal Policy is currently discussing whether to introduce a yearly NHI drug price revision. At present, drug prices are revised by the NHI every other year and drug prices are further reduced by various drug price policies. Introducing a yearly NHI drug price revision will have unintended consequences on Japanese patients by possibly hurting long-term access to vital, life-saving medications, and injecting an unnecessary delay in the Japanese healthcare system. EFPIA Japan strongly objects to a yearly NHI drug price revision for the following reasons:

1. The drug market itself is controlled by the NHI drug price revision performed bi-yearly and by the periodical reviews related to various drug price-suppressing policies. An NHI drug price revision conducted yearly will weaken efforts by pharmaceutical companies to develop and provide innovative new drugs. EFPIA Japan cannot support a NHI drug price revision conducted annually.
2. A precise survey of drug price is necessary to perform an NHI drug price revision. However, if the NHI drug price revision is conducted yearly, it is likely that the actual market price will not be accurately reflected for many newly marketed drugs and add an increased burden to stakeholders and wholesalers who are dependent upon these surveys and price negotiations. We fear that the price revision will not be based on the actual market price, which would increase the risk of even further delaying the establishment of new prices, and create more confusion in the system. Further, confusion in the market will renew the drug lag, create long-term access problems for patients, and ultimately deviate from the

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fundamental purpose of the NHI drug pricing system. The lack of predictability and stability will adversely affect wholesalers, patients, industry and other key stakeholders.

3. Owing to the government's various policies such as restructuring the clinical trial framework, improving the efficiency of regulatory reviews, and reorganizing the NHI drug pricing system to maintain the price during a patent period, amongst others, Japanese patients are gaining access to new drugs at the same level as patients in Western countries. This improved environment has also increased the likelihood that in the near future, a new drug will be approved first in Japan before elsewhere in the world. However, implementing a yearly NHI drug price revision will cause concern for investors, particularly foreign-capitalized pharmaceutical companies, who will be hesitant to invest in the Japanese drug market.
4. The medical fee reimbursement revision is performed every other year, and the number of drugs included in the medical fee reimbursement system is increasing. If the NHI drug price revision is conducted yearly, the balance between it and the bi-yearly medical fee reimbursement revision will be disrupted.

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