

Joint Statement on FY 2021 Drug Price Revision

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The Central Social Insurance Medical Council has recently compiled the Outline of the FY 2021 Drug Price Revision.

On behalf of the pharmaceutical industry, which aims to realize a society of healthy longevity through the development and stable supply of innovative drugs, we express our views as follows.

The Basic Policy for Fundamental Reform of the Drug Pricing System (agreed by the four Ministers on December 20, 2016; hereinafter the 'Basic Policy') referred to the off-cycle drug price revision in terms of 'conducting a drug price revision on products with a large price discrepancy'. Subsequently the Basic Policy on Economic and Fiscal Management and Reform 2020 (given Cabinet approval on July 17, 2020; hereinafter '2020 *Honebuto* Policy') stated that the 'FY 2021 drug price revision shall be fully reviewed and decided on taking into consideration the impact of the new coronavirus infection (COVID-19) and the content of the 2018 and other *Honebuto* Policies'.

With reference to the above background the pharmaceutical industry has held that the scope of the drug price revision should be limited to products of which the discrepancy rate between the NHI price and the market price is significantly greater than the average discrepancy rate of all listed products. However, it has been decided that the FY 2021 drug price revision shall be applied to products with a discrepancy rate of more than 5.0%, which is 0.625 times the average discrepancy rate of 8.0%, and the revision rate shall be relaxed by 0.8% as a "COVID-19 special exception". This decision deviates significantly from the background to the discussions following the

Basic Policy and the intent of the 2020 *Honebuto* Policy. At the same time it undermines the predictability of Japan's drug pricing system and is completely unacceptable. In addition, the market pricing status, the management status of medical institutions, pharmacies and drug wholesalers, drug development and stable supply and above all the impact of COVID-19 cannot be described as having been fully taken into consideration. We can only perceive the decision as a significantly unbalanced one in terms of achieving a balance between the 'reduction of the public burden' and 'improving the quality of healthcare'.

With a view to securing access to innovation in Japan and establishing a drug pricing system that is highly transparent and acceptable to the public and all stakeholders, we, the representatives of the pharmaceutical industry, will continue to participate in drug pricing reform discussions including the modality of the drug price revision.