

23 May 2023 | Analysis

Japan Readies One-Off Price Cuts For Big Sellers

Entresto Slashed By 15%

by **Lisa Takagi**

Japanese regulatory authorities have announced a set of additional reimbursement price cuts for selected products in August, under which Novartis's heart failure drug Entresto will see its price slashed by 15%. A batch of other newly approved drugs has also been priced.

Following the latest round of annual drug reimbursement price cuts announced in March and implemented in April, Japanese regulatory authorities have now announced additional extraordinary price revisions for five products, effective 1 August.

[*Daiichi Sankyo Co., Ltd.*](#)'s Tarlige (mirogabalin) and [*Viartis Inc.*](#)'s Lyrica (pregabalin), both neuropathic pain drugs, along with [*Novartis AG*](#)'s Entresto (sacubitril/valsartan) for heart failure and two breast cancer therapies - [*Eli Lilly and Company*](#)'s Verzenio (abemaciclib) and [*Pfizer Inc.*](#)'s Ibrance (palbociclib) - will all be repriced on that date.

All are subject to the Ministry's of Health, Labour and Welfare (MHLW)'s market expansion repricing scheme (☒☒☒☒☒☒) for products which have seen faster than expected growth under the country's National Health Insurance (NHI) system and will see their current tariff prices cut by 1% to 15%.

More immediately, the same scheme will also be applied to [*AstraZeneca PLC*](#)'s oncology drug Tagrisso (osimertinib), which will see its reimbursement price cut by 11% from 1 June. (Also see "[*Japan Price Revision: Mixture of Cuts And Increases Amid Supply Crisis*](#)" - Pink Sheet, 15 Mar, 2023.)

In a flurry of activity around pricing, the MHLW also announced the price-listing of a batch of

recently approved drugs to be included in the reimbursement tariff on 24 May.

August Market Expansion Repricing

The market expansion repricing scheme is aimed squarely at cutting NHI reimbursement costs for drugs that have grown well beyond initial official forecasts at the time of their original price-listing. The scheme is applied several times per year to products within 10 years of launch with reimbursement-level sales exceeding JPY35bn (\$253m) and at least double the original forecast.

The process continues to be strongly opposed by both domestic and international research-based pharmaceutical industry groups, with US association PhRMA, for instance, warning of the chilling effect on innovation in Japan of this and other price-related policies. (Also see "[PhRMA Promotes Cluster Concept In Japan Reform Wish List](#)" - Pink Sheet, 2 Nov, 2022.)

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Daiichi Sankyo reported Japan Tarlige revenues of JPY38.5bn in the fiscal year ended 31 March and is currently forecasting JPY41.4bn this fiscal year.

The market expansion rule was also applied to products with similar indications. For example, Lyrica will face a 1% cut because of its similarity to Tarlige as both are indicated for neuropathic pain.

New Rare Disease Drugs Priced

The 12 new products approved recently will be officially included in the NHI list on 24 May. (Also see "[Pipeline Watch: Nine Japanese Approvals And 16 Phase III Trial Updates](#)" - Scrip, 3 Apr, 2023.)

The group includes several therapies for rare diseases, including Orphacol (cholic acid) from Japanese venture ReqMed (co-developed with French firm Laboratoires CTRS). Expedited local development was recommended by Japan's Evaluation Committee on Unapproved or Off-Label Drugs with High Medical Needs.

[Takeda Pharmaceutical Co. Ltd.](#)'s global mainstay drug Entyvio (vedolizumab) added subcutaneous injection syringe and pen formulations, which are expected to contribute to already strongly growing sales. (Also see "[Record Revenues For Takeda But Headwinds Coming](#)" - Scrip, 11 May, 2023.)

Taiwanese bioventure [PharmaEssentia Corporation](#) received its first Japanese approval, for lead product Besremi (ropeginterferon alfa-2b) for polycythemia vera. Phase III trials for essential thrombocythemia and chronic myeloid leukemia are also ongoing in Japan, the firm notes.

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Israeli firm *MediWound Ltd.*'s NexoBrid was developed by *Kaken Pharmaceutical Co., Ltd.* in Japan under an April 2016 licensing deal.

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