



Position Paper

The use of Foreign Average Pricing for Medical Devices Marketed in Japan

Eucomed International Affairs Task Force

Issue: In setting reimbursement prices for some categories of medical devices, Japan's Ministry of Health, Labour and Welfare uses a reference pricing system. This system is based on comparisons with prices of similar products in the United States and selected countries in Europe. Some of those comparator prices are also fixed by national governments. Japan's reference pricing system results in a compounded loss of funds available to manufacturers for research and development of future generation medical devices – products from which patients and health care systems in Japan and world-wide demonstrably benefit. In addition, reference pricing does not fully account for differences in local conditions and costs of doing business in Japan.

Background information: The Ministry of Health, Labour and Welfare (MHLW) fixes the maximum reimbursement (National Health Insurance (NHI)) price for most medical devices on the market in Japan. In some cases, the NHI price for the device is included in the technical fee paid to the doctor or hospital for the procedure. In other cases, especially for cardiovascular and orthopaedic specialities, the price for "special treatment materials" medical devices is fixed separate from the technical fee.

The process by which such prices are established is time-consuming, burdensome, and opaque. In addition, for those devices for which a new "functional category" or new associated technical fee must be created, the process may be started only at specified times and only after the premarket approval safety review has been completed. This adds further to the delays, already substantial, in introducing new medical devices to the market (typically, new medical devices are approved and introduced in Japan 2-5 years later than they are in Europe). The length and unpredictability of this process discourages investment in innovative therapies and diagnostic tests.

Historically, MHLW has used the bi-annual "R-zone" permissible discount survey method to adjust NHI prices based on actual average selling prices in the national market for devices in each functional category. This process is based on the fact that sellers are permitted to offer their products at prices below NHI prices in hopes of gaining market share. Over the past decade, such R-zone-driven price reductions have averaged 6 to 7% per two year cycle. While Eucomed supports such a market-based approach, it must be recognised that this system does not differentiate between newer and older products that fall within the same functional category,

Beginning in 2002, and in addition to the existing R-zone mechanism, MHLW introduced a new "Foreign Average Pricing" (FAP) rule as the basis for foreign reference pricing of certain categories of medical devices (a similar rule for medicinal products had been introduced earlier). FAP is intended to adjust the prices of medical devices in Japan based on the simple average of prices for the same or



similar products in the U.S., Germany, France, and the United Kingdom. It does not, however, account for the fact that the markets in Germany, France, and the UK are entirely or substantially dominated by government purchasing and/or reimbursement.

The FAP method also does not adequately account for differences in the local costs of doing business. In addition, as compared to other markets, Japan retains a complex multi-layered distribution system and many inefficient small hospitals that perform procedures so infrequently they do not develop or retain the necessary expertise. All these factors lead to expensive ongoing technical support from manufacturers and importers independent of the size of the hospital. In addition, the costs to manufacturers and importers of compliance with Japan's burdensome regulations are large and growing.

Japan again used FAP to reduce reimbursements for devices in 2004. The final list of items subject to FAP reductions, as well as the severity of the payment cuts, was reduced somewhat due to significant pressure from industry. Nonetheless, price cuts based on FAP for some product categories were severe. From April 2002 to March 2006, it is estimated that reimbursement price decreases will have cost industry approximately ¥330 billion/€2.5 billion -- funds that are not available for investment in research and development.

By such policies, patients and the health care system in Japan essentially benefit from research and development funded by others.

MHLW justifies its application of FAP by citing a subjective perception that prices for medical devices are much higher in Japan than in the U.S. and Europe. However, the products most often cited account for less than 0,8% of total health care spending. Further price cuts for these devices will result in insignificant cost savings but indeterminate losses to individual patients and the health care system in general.

At the practical level, Eucomed is concerned about how comparison prices will be gathered, how they will be analysed, how they will be verified, and how comparisons will be made between prices for different products from several manufacturers in the same functional category. In addition, because of long delays in the approval of new medical devices in Japan, many products are no longer marketed in the comparator countries in Europe, so price comparisons are problematic and misleading.

More importantly, European industry is deeply concerned about the application of FAP as it has a disproportionate impact on importers to Japan. Most of the medical devices, both in volume and by category, currently subject to FAP are designed and produced outside Japan, many of them in Europe. FAP is an arbitrary price control mechanism that ignores the significantly higher costs of bringing advanced technologies to the market in Japan.

Due to these regulatory and reimbursement hurdles, patients in Japan lack or have delayed access to the benefits of many therapies and diagnostic tests readily available in other advanced economies. The FAP policy works against efforts to promote productivity, self-sufficiency, and reduced disability in Japan's ageing population. It also discourages competition and creates disincentives for the introduction of new products in Japan and investment in new technology research. FAP undermines the Government of Japan's stated interest in promoting technology innovation and foreign direct investment. Arbitrary and unpredictable pricing policies that do not account for the unique factors of the Japan market, as well as failure to address regulatory burdens, will drive investment to other markets, at the expense of



Japanese patients and Japan's economy. These longer-term costs far outweigh any potential short-term savings in the purchase of advanced medical technology.

Recommendations: In view of the above, Eucomed urges that the Government of Japan:

- (1) Give high priority to reforming the burdensome and unpredictable regulatory and price-setting processes that delay patient access to new medical technologies in Japan.
- (2) Permit premarket approval and price-setting reviews to run in parallel once the premarket safety review process has reached an appropriate stage.
- (3) Encourage reform of the existing distribution system and promote centres of clinical excellence.
- (4) Give priority to substantial reforms to address more significant underlying inefficiencies in the health care delivery system, e.g., lengths of hospital stay and number of hospital beds per capita.
- (5) Adopt policies that support ongoing private sector investment in research and development at attractive levels.
- (6) Engage in meaningful dialogue with the medical technology industry, including Europe-based industry, to create sustainable and equitable alternatives to the foreign average pricing system for medical devices.

About Eucomed: Based in Brussels, Eucomed represents the interests of the majority of the non-pharmaceutical European medical technology industry - a key sector that provides more than 100.000 products to hundreds of millions of patients in Europe and beyond. The industry provides jobs for more than 386.000 people in Europe and serves a market of some €55.2 billion annually - or 30% of the current world market. Eucomed represents directly and indirectly more than 3500 business entities active in the medical technology industry in Europe and beyond. Small and medium size companies make up more than 80% of this sector. Eucomed membership comprises some 24 national and pan-European associations and some 52 multinational medical technology manufacturers with a major European presence.