Hearing on the Implementation of the Pharmaceutical Industry Vision Action Plan

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DRUG PRICING

Drug Pricing - Fundamental Reforms

- New drug R&D investment requirements are enormous and increasing rapidly
- Value of innovation has diversified broadly, and is difficult to properly evaluate at launch under fixed pricing formulas

- **PhRMA urges MHLW to implement comprehensive reforms to ensure a globally competitive environment for innovative pharmaceutical and biomedical research.**
- **Now is the time to build a new system from the ground up, rather than engage in piecemeal modifications of the current system.**
- **The basis for a competitive pharmaceutical industry will be destroyed if the current system is maintained.**

Drug Pricing – Modifying Current System

- Japan's current system routinely reduces reimbursement prices for all drugs. As a result, drugs prices in Japan are well below average actual global levels over the patent life.
- This significantly reduces returns to expensive pharmaceutical research in Japan to levels well below other similarly developed countries. When combined with the comparator system, launch prices of new pharmaceuticals are significantly reduced.
- Maintenance of the current pricing system will result in the destruction of the research-based pharmaceutical industry in Japan.
- To maintain globally competitive life science industry and to ensure patient access to innovations, several amendments are urgently needed in the near term.

RECOMENDATIONS

I. New Product Pricing

- **Comparator Method:**
  - The initial launch price of the comparator (adjusted for post-launch inflation) should be used
- **Cost-Calculation Method:**
  - A manufacturer's suggested reimbursement price (MSRP) should be introduced, with the manufacturer allowed to choose between using MRSP or the cost calculation method
- **Premium Awards:**
  - The full range of premiums should be utilized in order to more appropriately recognize innovation. At a minimum new product prices should exceed the launch prices of old comparators.
- **Pricing Data Submission and Review:**
  - All relevant data, including that not in the Review Report from the Pharmaceutical Medical Device Agency, should be given serious consideration
  - The applicant should be able to represent itself at the first meeting of the DPO
- **Foreign Price Adjustment (FPA):**
  - A floor at 100% of the average four-country overseas price should be established
  - It is imperative that the four-country average be based on weighted averages, reflecting each country's share of the global market
  - Some adjustment should be made for those drugs not yet priced in other markets

II. Price Revisions of Previously Approved Pharmaceuticals

- **A-Zone Based Biennial Price Revisions:**
  - **The reimbursement system must be considered from a long-term perspective that recognizes the integrity of innovative pharmaceuticals without systematic or formulaic price reductions during the life of the applicable patent**
- **Re-pricing:**
  - **Re-pricing rules should be eliminated**

III. Pricing of Biologics

- **The current pharmaceutical pricing process is based on the characteristics of chemical entities, which do not recognize the unique characteristics of biologics**
- **MSRP should be used for pricing all biologics**
- **To fully respect the intellectual property rights of biologics, such products should not be subjected to extraordinary price cuts based on the absence of a product patent or length of time on the market**

IV. Insurance Coverage for All Appropriate Uses of Pharmaceuticals

- **PhRMA applauds MHLW's efforts to modernize labeling. However, in all such cases of a mandated labeling change to improve therapeutic use of a drug, the need for PMS must be reconsidered or minimized by using extensive global safety databases, and no price adjustments should be made as a direct consequence of such changes.**

V. Preventive medicine

- **Under the current healthcare system, medicines designed to prevent disease or minimize long-term recurrence of chronic disease should be reimbursed**

Drug Pricing:
Foreign Price Adjustment (FPA)

Importance of FPA Rule

- As long as NHI prices continue to be systematically reduced by various price cut mechanisms, foreign price adjustments for new drugs are critical to ensure globally competitive pricing
- Under the current pricing system, approximately 38% of new drugs are priced 25% or more below the average foreign price
- The upward adjustment function of the current foreign adjustment system is weakened by several particular rules (e.g., 2X cap, averaging of the adjustment ratio methodology which includes dosage forms for which there is no foreign price)
- Any rule changes which further increase the gap between Japanese and foreign prices should not be allowed
- Arbitrarily changing the FPA rule every two years introduces significant market risk and undermines the attractiveness of the Japanese market for R&D investments by innovative Japanese and foreign pharmaceutical firms

Does FPA Rule Only Benefit Foreign Companies?

- No.
- Since April 2002, prices for 60% of new drugs (42/71) were reviewed under FPA rules at the time of launch in Japan.
- Among these, 43% (18/42) were applied for by Japanese companies.
- Among 20 drugs which received upward price adjustments, 7 of them were applied for by Japanese companies.

Re. Referencing Countries

- **A realistic assessment of foreign pharmaceutical prices must take into account prices in key global markets, particularly prices in the U.S., which is larger than the entire EU market.**
- **U.S. prices reflect the level of R&D that is conducted in that market.**
- **Given the importance of the U.S. market, prices in the U.S. in no way can be considered an 'outlier' nor ignored.**
- **For the same reason, the US price should be referenced even if it is the only price available.**
- **In order to refine the current FPA rule, weighted-average prices should be used**

FPA for Non-Main Strength Medicines

- Prices for different dosage forms should be decided by manufacturers based on the features of the products and market conditions.
- However, the inter-specification adjustment is a fundamental component of the comparator pricing method
- Therefore, some degree of fluctuation with foreign price, both upward and downward, is inevitable. Nevertheless, the budget impact of such fluctuations is small.
- Current rules create a disincentive for firms to launch low dose forms in Japan if a foreign price for that dosage cannot be referenced.

PhRMA's Position on Foreign Price Adjustment

- It is necessary to set the floor at 100% of the average four-country overseas price
- It is imperative that the four-country average be based on weighted averages, reflecting each country's share of the global market
- Abolish the 2X cap for upward adjustment
- Some adjustment should be made for those drugs that have not yet been priced in other markets

CLINICAL TRIALS

- **Conducting clinical trials in Japan typically takes longer and is more expensive than conducting them in other major markets.**
- **Data presented at the Fourth Kitasato-Harvard Symposium in October 2003 suggests that Japanese clinical trials take much longer and cost about twice as much as they do in the west.**
- **As a result, the number of clinical trials conducted in Japan by Japanese and foreign companies has decreased rapidly.**
- **According to JPMA Database(2000), in 1990 18% of Japanese clinical studies started outside of Japan before they began them in Japan. But, by 2000 this figure had risen to 43%. And, this trend continues.**

Clinical Trails (cont.)

- **The difficulty of conducting clinical trails in Japan is a significant contributing factor why many commonly available global drugs are not yet available in Japan.**
- **A viable lasting solution must address systemic problems that inhibit companies from investing in clinical trials in Japan, not only in the R&D sphere, but also in the regulatory area (including broader acceptance of foreign clinical data as the basis for establishing safety and efficacy) as well as on the pricing front (where uncertainties about initial price levels and price stability add to the risk of seeing a return on one's investment).**

PMDA

- PhRMA welcomed the establishment of the PMDA April 2004 and its goal of shortening approval times.
- PhRMA agreed to pay user-fees roughly double those under the previous system with the shared expectation these fees would be used to hire more review staff, and increase transparency and efficiency of the new drug approval process.
- Unfortunately, we are very concerned as PMDA reviews are slowing down, rather than speeding up.
- PhRMA supported the adoption of policies to ration consultation slots, but only as a temporary response to a short-term crisis.
- PMDA's adoption and sharing of performance metrics is critical to improving its performance.

DATA EXCLUSIVITY

- **PhRMA strongly supports the establishment of data exclusivity provisions in Japan, and specifically the introduction of an eight-year data exclusivity period.**