- In the fiscal 2006 drug pricing reforms, the breakthrough and usefulness premium requirements were relaxed, premium rates increased and the graduated allocation of corrective premiums was revised. At the same time a new 'pediatric' premium category was established.

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- Acceleration of approval reviews The problems with the drug pricing system in terms of promoting and expanding the drug industry have been referred to. These include the impediment to healthy competition of a system in which prices fall continuously under the drug pricing criteria and special case reductions of original drugs etc. that are independent of market prices.
- These points are based on the philosophy that, to deliver high quality drugs to patients, it is vital to value innovation fairly and also to secure adequate profits and research funding to expedite the development of innovative and high quality drugs. On the other hand, the health insurance system, which includes the current drug pricing system, serves as a financial guarantee of access to healthcare by the whole nation and it can also be argued that in terms of system sustainability there are natural limits to the burden it shoulders.
- However, reform of the clinical trial infrastructure and review system and aspirations for a globally competitive market environment are crucial for the elimination of the drug lag.
- From this perspective, given the situation under the present drug pricing system where, even during the patent life, drug prices are structured to fall continuously and moreover are used for comparison in the calculation of drug prices, even the corrected prices of new drugs are likely to fall below the level in the major European countries and the US, leading to more increases rather than reductions on the application of the foreign price adjustment. In respect of drugs which thus are expected to be more highly priced abroad than in Japan, it has been pointed out that launch overseas gives more favorable drug pricing and that the pricing system has become unfavorable to domestic lead-off development.
- With reference to the above points, to assure a fair valuation of innovation, a globally competitive market and the sustainability of health insurance finances, discussion should be held on a mechanism for achieving returns during the patent life commensurate with the risks and innovation and allowing steady generic substitution on patent expiry and completion of the reexamination period. (Fiscal 2007)

  Matters such as the stable supply of drugs should be considered in conjunction with the review and implementation of the drug pricing system.

(5) Fostering of generic market

Action Plan based on previous Vision

- The promotion of generic drugs requires the establishment of the respective medical fees infrastructure. In the fiscal 2002 revision, measures such as the following were taken: ① Higher assessment for prescriptions that include generic drugs, ② Dispensing fee premiums for pharmacies dispensing and supplying information on generic drugs. In the fiscal 2006 revision, the prescription format was changed to facilitate the decision by physicians to switch to generic drugs.

- As a support package to enhance the reliability of generic drugs: ① An overview of 'Medical fees for generic drugs' was supplied on the MHLW Web site and ② Generic drug manufacturers have been instructed to make efforts to ensure stable supplies, improve the package insert information, provide an information supply framework and supply relevant information promptly

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- While innovative new drugs promote the quality of healthcare, the use of high quality and reasonably priced generic drugs reduces the financial burden and rationalizes health insurance finances. It follows that a balanced distribution of original and generic drugs is vital. The current status of the drug market does not allow generic drugs to fulfil their potential role.
- The reasons given for this include ① That the full trust of medical professionals cannot be won due to the existence of generic drug manufacturers with deficiencies in stable supply, information supply and other respects, ② That the doubts over the quality of frontline medical professionals have to be dispelled and ③ That pharmacies are concerned about matters such as the increase in stockpiles and dead stock and in the time spent on supplying information to promote generic drugs.
- The MHLW will therefore implement an overall package of measures, including initiatives to tackle issues such as stable supply and information supply, to ensure the steady achievement of the target of at least a 30% generic market share (double the current) by fiscal 2012 (16.8% by volume (fiscal 2004)) set out in the 'Program to Improve the Quality and Efficiency of the Medical and Nursing Services' (MHLW May 2007) (Fiscal 2007 ~)

(6) Fostering of proprietary drug market

Action Plan based on previous Vision

- In areas where self-medication is anticipated, the use as non-prescription drugs of suitable products shall be approved as appropriate with reference to the recommendations in the 'Status of Non-prescription drugs in Self-medication' (the interim report from the Panel on the Rationalization of Non-prescription Drug Approval Reviews). The aim is to promote the OTC drug market while ensuring global consistency through measures such as switching to OTC drugs those that the nation can use correctly of their own accord under the proper advice of a pharmacy or drugstore pharmacist or other specialist.

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- Although to pursue the concept of self-medication further it is vital to promote the effective use of non-prescription drugs, in recent years their market has been shrinking. Meanwhile, the market for drugs for specified health use has been increasing, which is inferred to be linked to the purchasing of health foods and supplements etc. as public concern is directed at disease prevention and promotion of health.

- On the other hand, given the further increasing ratio of elderly to the total population and also the diversification of the healthcare needs of the public, promotion of the effective use of non-prescription drugs calls for the development of non-prescription drugs, quasi-drugs and switch OTC drugs capable of responding to the new needs of the public.
- In particular, the promotion of 'switch OTC drugs' through the conversion of ethical drugs and the development of OTC drugs with new indications is expected to produce products with indications and effects beyond those required of conventional non-prescription drugs and thus to respond to the new health consciousness and other public trends (for example, the prevention of the metabolic syndrome, skincare benefits). Meanwhile, for the original developers of ethical drugs, conversion to switch OTC drugs enables consumers to purchase these drugs freely, expands their market and ordinarily imposes a three-year period of safety surveillance after acquisition of marketing approval. Therefore in terms of the new drug life cycle, this is considered to be an attractive market sector and further promotion of switch OTC drugs can be expected.
- Nevertheless in view of the high development risks involved with switch OTC drugs, the conversion to non-prescription drugs of the active ingredients of ethical drugs is currently not progressing smoothly, as is evident from the limited number of products approved as new switch OTC drugs over the last five years.
- Therefore, in compliance with the scheme deliberated and approved by the MHLW Committee on Non-prescription Drugs in March of this year for the conversion to non-prescription drugs of the active ingredients of ethical drugs, the conversion, while ensuring the transparency of the process, of those periodically considered suitable shall be actively promoted through discussion and publication by the Council on Drugs and Food Sanitation following requests to drug-related medical societies for draft summaries and hearings of their views. (Fiscal 2007 ~)
- In addition, the stumbling blocks in the filing of applications for the approval of switch OTC drugs and the provision of a highly prompt and transparent review system for their early launch should be discussed.
- Furthermore, the support of the public is vital for popularizing self-medication and expanding the OTC drug options, and the collaborative industry-government-university infrastructure required for this should also be discussed.

(7) Stremlining and grade-up of distribution function

Action Plan based on previous Vision

- To address issues such as the rationalization of drug distribution and inventory management, the computerization of medical institution and pharmacy operations and lot number labelling for the safety assurance of biological or similar products, the introduction of IT and standardization in the drug distribution sector has been promoted and implementation guidelines on the bar-coding of ethical drugs to prevent drug mix-ups and secure product traceability have been formulated.
- The 'Council for the Improvement of Ethical Drug Distribution' (established in June 2004) compiled an 'Interim Report' (December 2004) and the 'Handling of Returns' (March 2006) concerning the correction of inappropriate drug trade practices such as pending price settlements and provisional deliveries. In addition, the Outline of Fiscal 2006 Drug Pricing

Reform (approved by Chuikyo) set out the plans to correct these long-term practices, to which end a guidance notification based thereon was issued to NHI medical institutions, NHI pharmacies, drug wholesalers and the heads of other related organizations. Updates on the situation have been made through status surveys of price settlements and requests for improvement have been made to the respective trading parties.

Action Plan for New Drug Industry Vision

[1] Actions to rationalize ethical drug distribution and correction of inappropriate trade practices

- To correct inappropriate trade practices such as pending settlements, provisional deliveries and global pricing, which could undermine the trust in the current drug pricing system and surveys, the 'Council for the Improvement of Ethical Drug Distribution' shall hold itemized discussions with a view to compiling further remedial measures. (Fiscal 2007)
- In addition, the Council shall regularly conduct status surveys of price settlements etc., publish the results and request remedies from the respective trading parties based thereon. (Fiscal 2007 ~)

[2] Further promotion of IT and standardization

- Standardization of ethical drug code labels will assure medical safety through post-marketing product traceability and the prevention of drug mix-ups. Bar-coding on a per package basis by manufacturers and marketers is also called for to rationalize drug distribution and inventory management.
- The 'Implementation Guideline for Bar-coding of Ethical Drugs' was set out in September 2006 concerning ethical drug code labelling, and efforts are being made to publicize the requirement in principle for proper bar-coding with the mandatory label items for all products shipped with effect from September 2008. Further guidance shall be given on the actions to be taken, such as surveys on the implementation status of pharmaceutical companies. (Fiscal 2008 ~)
- In addition, in terms of anti-counterfeit drug measures, product recalls and other distribution management rationalization measures, surveys of voluntary label items shall also be conducted to check their bar-coding status, application and other actions taken. Pharmaceutical companies shall be encouraged to take early action to implement this voluntary labelling on a per retail package basis and subsequent expansion of the scope of labelling shall be discussed. (Fiscal 2008 ~)

(8) Promotion of proper use of pharmaceutical products

Action Plan based on previous Vision

- With reference to the recommendations of the 'Council on Drug Information Supply', the Pharmaceuticals and Medical Devices Agency prepared and released a 'Supply of Information on Drugs and Medical Devices Website" to supply safety information and evaluations thereof to medical professionals, patients and the public. In addition, this

website also gives the latest package insert information and drug guides for patients and the public.

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- To ensure the safe supply of drugs, the Pharmaceutical Affairs Law imposes duties on manufacturers and marketers such as the inclusion of necessary particulars in package inserts etc. In addition, the collection of package inserts etc. should allow the optimum treatment for patients to be selected at the medical frontline.
- Pharmaceutical companies are primarily responsible for supplying the medical frontline with the necessary information on drugs through package inserts etc., and the 'Panel for the Prompt Supply of Effective and Safe Drugs' holds that for the post-marketing safety of drugs care should be taken to make the information given therein as clear as possible. To this end the following actions are necessary:

    a. To modify the warnings in package inserts to ensure that the necessary details are clearly and plainly understood in proportion to the effect on the patient, through giving prominence or fine-tuning the "Warnings of potentially life-threatening adverse effects on patients"

    b. To supply information to patients through the further constructive preparation and use of 'Drug guides for patients'. (Fiscal 2007 ~)

(9) Arrangement of the promotion system by the public and private sectors ('Five-Year Strategy for the Creation of Innovative Drugs and Medical Devices')

Action Plan for New Drug Industry Vision

[1] Public-private dialogue

- On January 31 2007 hosted by the Minister of Health the 'Public-private dialogue for innovative drugs' was inaugurated and attended by the Minister of Education, Culture, Sports, Science and Technology, the Minister of Economy, Trade and Industry and representatives from the pharmaceutical industry and educational and research institutions etc. The aim of the dialogues is to gain a common perception on the creation of innovation in the drug field and enhancement of the global competitiveness of the drug industry. A second public-private dialogue was also held, on April 26 2007, at which the 'Five-Year Strategy for the Creation of Innovative Drugs and Medical Devices' was agreed. These dialogues shall continue to be held around once or twice a year, and progress checks on the Five-Year Strategy shall be carried out regularly. (Fiscal 2007 ~)
- In addition, a subordinate liaison unit shall be established by the relevant ministries, research institutions and industry, which shall also carry out functions such as coordinating the views on the subjects of priority areas for drug and medical device research, the policies for the nurture of venture firms and the provision of the clinical research and trials infrastructure. Where necessary a forum for public-private dialogue at all levels shall also be provided, since discussions on the future status of the drug industry should also be considered. (Fiscal 2007 ~)

[2] Establishment of research framework

- To push ahead with this Vision and the 'Five-Year Strategy for the Creation of Innovative Drugs and Medical Devices' the Health, Labour and Welfare administration shall consolidate the framework for promoting drug and medical device research and commercialization and for enhancing the global competitiveness of the industry. (Fiscal 2008 ~)

Conclusion

Since the drugs supplied by the drug industry have a major impact on the life and health of the nation and also have a bearing on medical insurance finances, an even higher level of ethics, reliability and transparency is called for from this industry than from industries in general. Further, the drug industry is now attracting unprecedented attention, as evidenced last year by the changes in the national perception of drugs and the industry and the expectations placed on it by the government as a growth industry. Greater political correctness in corporate behaviour, an open business structure, compliance with the code of practices and other efforts to maintain the trust of the public are called for. The government should also support the drug industry and implement public-focused policies to ensure the prompt delivery of world-leading drugs to the nation.