PRICING AND REIMBURSEMENT

(Japan)

INTRODUCTION

Japan has a public and compulsory health insurance system, as a part of the national social security system. At present, both are being reorganised as the completion of the structural reforms is expected by the end of year 2002.

Organisation of the health insurance system

The health insurance system in Japan was founded in 1922 with the enactment of the Health Insurance Law. From 1961 the health insurance has been expanded to cover the entire nation. Currently, the health insurance is mandatory not only for all Japanese nationals and citizens, but for the residents of Japan as well. The health insurance system in Japan differs from health insurance programs in the other industrialised countries. All insurers are organised into seven associations (organisations) such as those of the national government, municipal governments, health insurance unions, cooperatives, individual industry associations and so forth. There are two principle types of health insurance programs:

- Employees' health insurance programs - all civil servants in the central, prefectural and municipal governments, and the employees of the commercial enterprises of any type are mandatory enrolled in the some employees' health insurance program. The immediate families of the insured (spouses, dependent children) are also covered.

  The employees' health insurance programs are operated by various societies, usually organized by industry type, and in some cases – regionally. Individual companies or a group of companies may organise a health insurance society. The health insurance societies serve as insurers of the health insurance programs managed by the society. It is reported that the number of those health insurance societies in Japan is about 2,000.

Most of the health insurance societies are members of the National Federation of the Health Insurance Societies (NFHIS, *Kenporen*). The NFHIS is an institution representing the interests of the payers of the medical bills, and thus it is lobbying actively at the meetings of the Central Social Insurance Medical Council (*Chuikyo*) .

Payment to the employees' health insurance programs are automatically deducted from the monthly salaries in a similar way as the payment for the employee's pension and the withholding of the income tax. The contributions to the insurance funds are equal between the employees and the employer, and supplemented from the national budget.

The standard benefit from the society-managed health insurance programs is the covering 80% of the medical bills for those who are employed and 70% for the dependent family members. The patients may be further refunded if the annual amount of the cost for the medical bills exceeded a predetermined amount, or subjected of a highly advanced treatment (transplantation, etc.), or have received treatment abroad.

- National Health Insurance (NHI) program – covers all not insured by the employees' health insurance programs, such as retired persons, free-lance or self-employed, and others. It is operated regionally by the local (municipal) governments.

  Payments to the NHI program are to be provided by the insured person in a way designated by the local government.

All insured persons are issued a health insurance certificate what for many – such as children, housewives and elderly without a driver's license or an overseas passport, is the only document for self-identification. From year 2000 the certificates are permitted to be issued not only in a paper form, but also as plastic cards, including with integrated circuit (IC) for instant payment.

Under both the employees' health insurance programs and the National Health Insurance (NHI) program the medical benefit is provided to the patients in a form of actual medical treatment. In some limited cases, the funds may be provided in advance

or after as cash reimbursement to compensate for the medical treatment. The medical treatment includes both the medical procedures and the prescribed medicines, and generally the system in Japan is defines as “fee-for-service system”.

In a typical case, when an outpatient visits a hospital or clinic for medical check, treatment or procedure, upon completion of the visit a bill is issued and it should be settled at the spot. If the hospital or the clinic does not operate under the system for separation of the prescription from dispensing practice (*Bungyo*), the patient should pay the necessary cost for the medical procedures and for the prescribed medicines. If the prescription and the dispensing practices are separated, the patient should pay once in the hospital for the received service and then in a pharmacy – for the prescribed medicines. At both occasions, the patients should produce the health insurance certificate as a proof for being insured.

Payments for medicines – regardless received in the dispensary of the medical institution, or purchased in a pharmacy with a doctor’s prescription are uniformly 20% (in the case the patient is not the principally insured – 30%) of the cost of the medicine. However, the cost of the medicinal products – such as proprietary medicines , which can be bought without a prescription in the pharmacies, drugstores, convenience stores etc. should be paid in full.

Aside from the mandatory health insurance programs, there is a number of private health insurance options – offered by domestic or foreign insurers with benefits such as covering the remaining 20 or 30% of the medical expenses incurred by the patient, reimbursement for expenses not covered by the national insurance programs – such a those charged for assistance in giving birth and so forth.

A very limited number of hospitals (mostly in the metropolitan areas) may accept some foreign health insurance certificates in individual cases.

General principles of the pricing and reimbursement

In Japan at present both the pricing process and the reimbursement rates are tightly regulated by the authorities.

The healthcare insurance system in Japan has been designed to guarantee to all enrolled – regardless of their income level – at any time and at any place in this country medical treatment and services acceptable both in term of the quality and price. However, over the years this system has resulted in an enormous burden to the national coffers and presently the Government is seeking a way to curb the health and social care expenditures. The ruling political coalition created the Social Security Reform Council – as an advisory body to the Government in order to device a wider plan for carrying out reforms in the social security systems, including health insurance and the healthcare for elderly. A radical reform in the latter two fields is expected to be concluded in 2002, with focus on health insurance, medical fee payment, and NHI price system.

The current status of the pricing and reimbursement system in Japan is also bound to be changed in the fiscal year 2002. On a meeting on March 30 the Cabinet decided to proceed with a new Three-Year Plan for Promotion of Deregulation, starting April 1, 2001 and expected to be completed by the end of FY 2003. The previous Three-Year Plan for Promotion of Deregulation (1998-2000) brought the wide range of administrative reforms including in the central government and the Ministry of Health, Labour and Welfare. The medical spending for the fiscal year 2001 is projected at 30.7 trillion yen (approximately – 250 billion US$) and 7.2 trillion yen are expected to be paid from the state, as the remaining by the insurers. The largest part – about 50% go for payment of healthcare workers (physicians, nurses, etc.) while pharmaceutical bills account for nearly 20 %. In contrast to other countries, in Japan there is no imposed maximum of the payable national expenses and the Council for Economic and Fiscal Policy – an advisory body to the Government is expected to develop in 2001 a plan to curb medical spending, especially among elderly.

In a commitment to the deregulation – in parallel with the ICH process, and international obligations of Japan there are continuous efforts for deregulation related to pharmaceuticals and medical devises .

The current system for formation of the prices of the medicinal products is outlined below:

Prescription medicinal products

Largely, the medicinal products approved for reimbursement are the prescription

medicines. Certain types of products – although available on a prescription basis only, should be paid in full by the patients, since they are not included in the reimbursement list. Typical examples are higher quality dental materials, certain medical devices for correction of the vision, and some of the "life-style drugs" – such as Viagra or low-dose oral contraceptives.

After receiving the Manufacturing and Import Approval the holder can initiate the distribution immediately without the product being included in the National Drug Tariff List and therefore ineligible for reimbursement. However, this is very uncommon practice and the majority of the manufacturers apply for initial price determination.

The determination of the reimbursement prices **PRICING** of newly approved products is done based on the application by the holder of the Manufacturing and Import Approval, the hearings in the Economic Affairs Division of the Health Policy Bureau and subsequent deliberations in the Medical Economics Division of the Health Insurance Bureau of MHLW, the review and the proposal of the Drug Pricing Organisation, **DRUG PRICING ORGANISATION** and report and approval by Chuikyo before the authorisation by the Minister of Health, Labour and Welfare. The newly listed products are published quarterly in the Official Gazette.

The entries of generics into the NHI price list are permitted once a year and a different method is used for the calculation of their prices. **PRICING**

The prices of the medicinal products already listed in the National Tariff List are subjected to a biannual revision – most often downward, and in a similar way are announced publicly. The current system named - "the weighted average price plus fixed allowance system" was deployed in 1991 and the first price revision **PRICE REVISIONS** introduced in 1992, the latest – in 2000.

After the conclusion of either the process of initial pricing or of re-pricing the medicinal products become eligible for reimbursement. **REIMBURSEMENT** There are certain commercial sources – such as Directory of Pharmaceuticals used for Medical Services Covered by Health Insurance, publishing the names and prices, and other data of the reimbursed poducts.

Proprietary medicinal products

In principle the prices for medicinal products not eligible for reimbursement (or in rare cases – opted for not applying for reimbursement) are determined by the holder of the Manufacturing and Import Approval and/or License using rules not different than those for other commodities on the market.

Prices of both prescription and proprietary medicines are scrutinised by the Japan Fair Trade Commission as the main focus is on the distribution chain – sales at unfair market prices, unjustifiable rebates, formation of cartels by wholesalers to fix the prices for certain categories products, and so forth.

REGULATIONS

Laws

From legal and regulatory points the practice of pricing (including re-pricing) and the reimbursement in Japan is one of the most highly regulated. The original Health Insurance Law introduced in 1922 has provided health insurance to certain major occupational groups. However, the subsequent amendments and especially those in 1958 and 1961 switched the focus of the law to the residents and ultimately – to the provision of universal health insurance. The main reason for the higher degree of the regulation is that the health insurance system in Japan covers all residents thus leading to both comprehensive protection and increased spending, what in turn further steps up the regulation efforts. The public health insurance system has been established with the enactment of the Health Insurance Law, as at present there is a set of legislations dedicated to the health insurance of the residents and specific employees groups:

- Health Insurance Law (Law No. 70 of 1922)
- Law for the Partial Revision of the Health Insurance Law (Law No. 77 of 1984)
- Law for the Partial Revision of the Health Insurance Law (Law of 2000)
- National Health Insurance Law (Law No. 192, 1948)
- Law for the Partial Revision of the National Health Insurance Law (Law No. 53 of 1995)
- Nursing Insurance Law (Law No. 123 of 1997)
- Law for the Enforcement of the Nursing Insurance Law (Law No. 124 of 1997)
- Sailors' Insurance Law (Law No. 73 of 1939)
- Salaried Employees Health Insurance Law
- Social Insurance Council Law (Law No. 47 of 1950)
- Law of the Social Insurance Board (Law No. 206 of 1953; including the ordinances pursuant to this Law)
- Medical Service Law (Law No. 205, 1948)

The latest amendment of the Health Insurance Law introduced in November 2000, includes the abolishment of co-payments by elderly patients (those 70 years old and over) and revisions of the limits of payments from low-income families. At present, the elderly patients may choose between two systems – flat sum reimbursements system and flat rate reimbursements system, and the medical institutions are obliged to notify the patients which system they use.

Although the Medical Service Law is regulating areas other than those covered by the Health Insurance Law the both laws are often amended in parallel. Medical services are performed in the medical facilities and require payment of medical fees, which may include payment for the services, treatment and medicinal products prescribed.

Enforcement

The enforcement of the Health Insurance Law is a responsibility of the Health Insurance Bureau, HIB of the MHLW along with the implementation of the related regulations:

- Enforcement Ordinance of the Health Insurance Law
- Enforcement Regulations of the Health Insurance Law

The latest amendments to the enforcement regulations are from December 6, 2000. After the reorganisation of the central structures of the Japanese Government and the establishment of the Ministry of Health, Labour and Welfare, MHLW the new Social Security Council is reviewing the basic issues and recommending the policy regarding the health insurance, including the reimbursement prices.

Guidelines

The Health Insurance Law and other related laws create a framework of the health insurance system. The implementation of those laws is ensured by a number of other regulations included in such documents as various notifications, instructions, guidelines

and Question & Answers (Q&A) from the authorities.

Out of the matters with higher importance are the correct calculations of the fees charged to the patients in the medical facilities. The fees may include the cost for different procedures, diagnostic tests and other procedures, the prescribed medicinal products, fees for nurses and so forth. The correct calculation of the fees is of a critical importance, especially for the medical institutions (hospitals, clinics, nursing homes) ran as enterprises. Both cases of criminal padding of the expenses (overcharging the fees) and bankruptcies due to inappropriate charges in the fees were reported in the recent years.

The basic regulations are stipulated in the

MHW Notification No. 54 dated in March 1994
Rules to Calculate Treatment Fees According to the Health Insurance Law

Those basic rules are constantly supplemented due to introduction of new therapeutics products or new therapeutics approaches. One example is the eradication therapy for Helicobacter pylori in patients with gastric or duodenal ulcers. This is a complex disease and there is a variety of treatment options, including the choice of antibiotics. However, according to a recent Q&A type guideline released in December 2000 by the Medical Economics Division of the Health Insurance Bureau of (then) MHW, only specified antibiotics and other medicines, diagnostic kits, analytical procedures, etc, all applied within specified treatment period are eligible for reimbursement.

Aside from the new therapies, another topic of increased importance is the substitution of brand medicines with generic equivalents. Since under the current system patients have little incentives to opt for the cheaper (and altogether have almost no understanding of the prescribing process) alternatives, the efforts of the authorities are oriented to promote the use of generics among physicians.

Organisations

Since the prices for medicinal products and the pricing and reimbursement

practice and regulations are among the most important issues in the healthcare reform, aside form the authorities, a number of other organisations – industrial, professional or regional, national and international, are actively involved in the process of discussing, making proposals, lobbying, participating in hearings, working with their members and so on to contribute to the final result, expected in the year 2002. Below is a list of some of the major organisations:

National

- All-Japan Druggist Association, AJDA (*Zen-nihon Yakushusho Kyokai*)
- All-Japan Federation of National Health Insurance Organisations, AJFNHIO (*Kokumin Kenko Hoken Chuokai, Kokuho Chuokai*)
- All-Japan Hospital Association, AJHA (*Zen-nihon Byoin Kyokai, Zennichibyo*)
- Association of Japanese Healthcare Corporations, AJHC (*Nihon Iryo Hojin Kyokai*)
- Ethical Manufacturers Association, EMA (*Iyaku Kyogo Kyogikai*)
- Federation of Japan Pharmaceutical Wholesalers Associations (*Nihon Iyakuhin Oroshigyo Rengokai, Oroshiren*)
- Federation of Pharmaceutical Manufacturers Associations in Japan, FPMAJ (*Nihon Seiyaku Dantai Rengokai, Nichiyakuren*)
- Japan Bulk Pharmaceutical Manufacturers' Association (*Nihon Genyaku Kogyokai*)
- Japan Medical Association, JMA (*Nihon Ishikai, Nichii*)
- Japan Pharmaceutical Association, JPA (*Nihon Yakuzaishikai, Nichiyaku*)
- Japan Pharmaceutical Manufacturers Association, JPMA (*Nihon Seiyaku Kogyo Kyokai*)
- National Federation of the Health Insurance Societies, NFHIS (*Kenporen*)
- Osaka Pharmaceutical Manufacturers Association, OPMA (*Osaka Iyakuhin Kogyo Kyokai, Daiyakkyo*)
- Proprietary Association of Japan, PAJ (*Nihon Taishuyaku Kogyo Kyokai, Taishuyakkyo*)
- Pharmaceutical Manufacturers Association of Tokyo, PMAT (*Tokyo Iyakuhin Kogyo Kyokai, Toyakkyo*)

International

- American Chambers of Commerce in Japan (ACCJ) – Subcommittee on Medical Equipment and Supplies
- European Business Community (EBC) - Pharmaceuticals Committee
- Pharmaceutical Research and Manufacturers of America (PhRMA) – Japan Executive Committee

Both domestic and international organisation – representing a variety of parties and interests are actively lobbying, discussing and making proposals in the filed of health insurance, medical expenditures, price and reimbursement of medicinal products.

THE DRUG PRICING ORGANISATION

Establishment

The decision for the establishment of the Drug Pricing Organisation was taken on August 25, 2000, and its eleven members approved on September 27, 2000 by the Central Social Insurance Medical Council (*Chuikyo*) . The Drug Pricing Organisation was formally inaugurated on October 1, 2000.

There is absolutely no affiliation between the Drug Pricing Organisation – described here, and the Drug Organisation – a commonly accepted abbreviated name of the Kiko or the Organization for Pharmaceutical Safety and Research (OPSR).

Functions and authorities

The main function of the Drug Pricing Organisation is to set the prices under the health insurance system. The Drug Pricing Organisation shall decide on the proposed prices after internal review and hearing conducted by MHLW.

The first session of the Drug Pricing Organisation was held on January 9, 2001 and the first reviewed proposals were for the products approved by (then) Central Pharmaceutical Affairs Council, CPAC in the October-December 2000 period.

PRICING

After being granted a Manufacturing and Import Approval the holder (the manufacturer or a licensee) is legally permitted to start the sales of the product. From the point of reimbursement **REIMBURSEMENT** there are two options:

- Marketing without reimbursement
- Marketing with reimbursement

The procedure and the results of those two options differ significantly.

Marketing without reimbursement

Pricing of the medicinal products without reimbursement

Several types of products fall into group of medicinal products marketed in Japan without reimbursement:

1. Proprietary medicines – used for self-medication and sold without prescription as OTC. However, it is allowed and some products may have also a reimbursement price and when dispensed by prescription to be reimbursed as described below.

2. Certain products from the category of the prescription medicines , which applications for reimbursements have been rejected. Recent examples of this group are the higher quality dental materials, certain medical devices for vision correction, and the "life-style drugs" – such as Viagra or low-dose oral contraceptives.

3. Prescription only products for which for certain reasons, the holder of the Manufacturing and Import Approval has opted not to apply for reimbursement. This is rare and usually it is done to shortcut the waiting

period of up to three months for the reimbursement approval.

4. Prescription only products for which the holder of the Manufacturing and Import Approval after applying for reimbursement and the subsequent hearings and deliberation for price determination **PROCEDURE FOR PRICE APPROVAL** remained unsatisfied with price proposed and has withdrawn the application.

5. Delisted products – products that for certain reasons such as prescription-to-OTC switch have become ineligible for reimbursement.

The prices for the medicinal products sold without reimbursement are determined by the commonly accepted pricing formulas similar to other commodities, and taking into consideration factors such as the R&D expenditures, production and distribution costs, prices of similar or the same group products on the market, and so forth. However, as deregulated products – outside the governmental control exercised in the reimbursement practice, their sales and distribution are monitored by Japan Fair Trade Commission for unfair market prices and rebates, and especially – for the formation of cartels to fix the prices for certain categories products in the matured segments of the market – such as vitamin preparations, cold remedies, etc.

Distribution of medicinal products without reimbursement

The distribution of the medicinal products without reimbursement follows the manufacturer/importer – wholesaler – retailer chain, as the purchase prices are negotiated at each stage. The size of the market for proprietary medicines in Japan is about 14% of the total market for medicines. The distribution system for not reimbursed medicines consists of a system of national and wholesalers and two retail channels:

A) Licences retail outlets – according to the Article 24 of the Pharmaceuticals Affairs Law only proprietors of pharmacies (pharmacists) and the persons who are granted a business licence to sell medicines can be legally engaged in selling or giving medicinal products. Four levels of licences with different requirements and fees can be obtained:

- First class reseller drugstores (supervised by a pharmacist)

- Second class reseller drugstores (without a pharmacist)
- Third class reseller (Exceptional license) – case-by-case licence granted for reselling in remote areas with no other personnel for a limited numbers of products
- Household distributor-class reseller – restricted for both the product line and operational area

While the first two groups pharmacies and drugstores supervised by a pharmacist can handle all and any type of proprietary medicines, the latter three categories fall under certain restrictions.

B) General merchandise outlets – after the sales deregulation in 1999 outlets such as convenience stores, groceries, station kiosks, etc. can sales certain types of proprietary medicines and quasi-medicines, as the range of permitted products is expected to be expanded.

From March 1997, all non-prescription medicinal products have been removed from the Resale Price Maintenance Contract System as the retailer became free to set up the retail prices for those products. Recently (May 2001) it was reported that some retail outlets have started to display on the price tag of each product sold the price they have bought the products from the wholesalers – a practice, while not illegal, vehemently objected by both wholesalers and manufacturers.

Marketing with reimbursement

After obtaining a Manufacturing and Import Approval, the holder or its licensee can start selling the product immediately without the product being included in the National Drug Tariff List and therefore ineligible for reimbursement. However, this is very uncommon practice and the majority of the manufacturers apply for price determination.

Pricing of the medicinal products with reimbursement

While for the medicinal products without reimbursement the price can be freely set initially and subsequently revised upward or downward, for the medicinal products

under the reimbursement system, the initial pricing and the following periodical revisions are done according to two – regulated by the Government – procedures.

Calculation of the prices of newly approved medicinal products

From the point of determination of the price, the medicinal products eligible for reimbursement in Japan can be divided into two groups:

- Products representing New Chemical Entities (NCEs)
- Generic products

Types of prices for medicinal products with reimbursement

The medicinal products with reimbursement should have three different types of prices:

- ✓ Shipping price (manufacturer's invoice price) – this is a price determined by the manufacturer based on the various factors.
- ✓ Wholesaler buying price – this is the price for buying the product from the manufacturer and it is higher than the shipping price. The differential represents the sales margin.
- ✓ Wholesaler selling price – this is the price for selling the product to the end-purchaser (medical institutions) and it is higher than the buying price. The differential represents the distribution margin.
- ✓ Tariff rate – price of the products included in the National Drug Tariff List for reimbursement **REIMBURSEMENT** . It is always higher than any other price.
- ✓ Final purchase price (cost ofacuisition) – it is the price for purchasing the products from wholesalers, as in some cases the medical institutions may receive a rebate, thus further reducing the final cost for purchasing the product. The differential between the final purchase cost and the tariff rate is one type of operating margin for the medical institutions and a revenue source.

The definition of the prices of the newly approved medicinal products is based on several considerations such as:

- Existence of similar – by composition or effect products already on the market
- Comparison with other countries
- Premiums for innovativeness or usefulness

Price adjustment after similar efficacy comparison

There are two comparison methods – method I and method II, and they are applied when there is at least one other product already on the domestic market. The product selected for comparison is called a comparator and usually it is either with similar chemical composition or similar/identical approved indications and therapeutic effects. The price of the new products is based on the daily price – the cost of medicine used for one-day treatment - of the comparator product, with premiums added if judged as necessary.

The current system of selected comparator products is scheduled to be abolished from fiscal year 2002. In June 2000, the (then) MHW established the "Drug Classification Committee for a Selection of Comparator Medicines" – as a dedicated advisory body to the Director-General of the Health Insurance Bureau of MHLW with the task to create a new system for comparator products during 2001 and to present it to Chuikyo for approval. The current system of comparator products was modified in 1998 by Subcommittee of Institutional Planning of the *Ifukushin* (The Medical and Insurance Welfare Council). However, this latest modification – mostly classifying anti-ulcer, antibiotic, anti-inflammatory and antihypertensive medicines would be fully overhauled by the new classification system.

Price adjustment after comparison with foreign countries

The price adjustment based on a comparison with the prices in other countries is usually done when there is no suitable comparator product on the domestic market. However, there are no restrictions for adjusting the price after an initial price is given based on a comparison with a domestic product. The practice for coordination with

foreign reimbursement prices has been put into effect from April 1, 1996.

The Economic Affair Division of the Health Policy Bureau of MHLW is conducting regular surveys on the prices of both prescription and non-prescription medicines in various countries or for the purpose of some dedicated studies – in large metropolitan areas in Europe, North America and Asia. The results of those studies usually reflect the trends in the prices of some categories of medicinal products and medical devices. In contrast, for the price determination – the prices of individual products are taken as reference.

Four countries are accepted to be used as "comparator-country" – USA, two EU regions countries – Germany and France, and UK. Depending on where the same or similar products are registered, the domestic price may be revised upward or downward. While it is generally acknowledged that the prices in USA are higher and an US price used as a reference may lead to a higher domestic price, a comparison with the prices in France – country known for cheaper health insurance and medical costs, may result in a lower price of the domestic product.

The system for price adjustment based on a comparison with prices in foreign comparator countries may lead to certain controversial results and criticism. If assuming that two new products - product A and product B are given an initial price based on similar efficacy method with an already marketed product C. Normally, they will receive quite similar prices. However, if further the price is adjusted in comparison with the price in foreign countries it may result in significant discrepancy. If happened that the product A is marketed in USA only and product B is marketed in France only, the price for the product A in Japan is likely to be revised upward and the price for the product B – to be revised downward, what – as it has been reported - may produce a four-fold differential.

Similarly to the system for comparator products, is expected that the current system for comparator countries would be reassessed and modified. At present the Expert Subcommittee on NHI Pricing Affairs and the Medical Economics Division of the Health Insurance Bureau of MHLW are working on a revision of the system for comparator countries based on the two main concerns – the relevance and reliability of the list of US prices for medicinal products and whether the selected four countries are the proper choice for comparison with Japan. From one side, those

countries and Japan are the most industrialised in the world, but in terms of their healthcare systems – including health insurance system, pharmaceutical benefits, patient's co-payment in pharmaceutical cost and the (existence of a) government imposed ceiling of the medical spending, there are significant differences. If not abolished, the system for comparator countries is expected to be modified in 2002 in line with the other healthcare reforms.

Premiums

Another factor in the determination of the prices of the newly approved products is the system to grant "premiums" to selected products based on considerations such as innovativeness, usefulness or complexity of the products.

- Premium for innovativeness – basically the premium for innovativeness is reserved for "first-of-a-kind" products, products of new therapeutic categories or method of application and so forth. This premium may be down-revised and reduced, if there is a similar product already on the market and the new product is judged to have little or no innovativeness. The premium for innovativeness is the largest and set up to 40 % mark up.

- Premium for usefulness I and II grade – this premium is largely reserved for new products showing higher or superior efficacy compared to similar product(s) already on the market. The two grades of the premium for usefulness are set up at 10 and 3 %, respectively.

- Premium for market size I and II grade – depending on the projected/captured market size. The two grades of the premium for market size are set up at 10 and 3 %, reversely to their market share: the products with very small market share might be awarded 10 % premium, while products with small share – 3 %.

- Premium for kit – products representing kits or combination products, and developed through certain modifications are called "reported products" (*hokoku hinmoku*) when included in the price list. They might be given a mark-up in the price as an acknowledgement for the complexity

of the product, thus reflecting the higher development and manufacturing cost.

Price determination without comparison (cost calculation method)

In certain cases – such as the product being first of a new type to be approved in Japan or even the Japan to be the country of the first launch, neither the method of "price setting by comparison to similar pharmaceuticals" nor an adjustment of the price based on comparison with other countries can be used. Instead, the "cost accounting system" – or cost calculation method is applied. The prices in such cases are determined by a "cost accounting system" which calculates prices by summing up the production costs, selling, general and administrative expenses, business profits, distribution costs, and so forth. Recently, several flaws in the cost calculation methods were targeted for revision – such as the failure of the method to take into account the widely varying expenses for sales activities and general administrative cost depending on the market share.

The applicant may submit a request the price of the product to be determined by cost calculation method to avoid the determination by using similar efficacy comparison method, however the authorities reserve the rights to select the actual method for price determination.

It is expected that the cost calculation method shall also be revised along with other changes in the health insurance system, so to reflect more accurately the R&D expenditures, depreciation of the investments and other factors.

Prices for long-term therapeutic courses

Under the current system for the newly approved products are not allowed to be used in long-term therapeutic schemes. It is supposed that after one year collecting of information for the adverse events as a part of the pharmacovigilance , the safety of use shall be additionally confirmed and only after then the long-term therapy permitted. According to the individual products and indications, in some cases the treatment courses might be as extended as life-long. Therefore, in certain categories –

such as psychiatric disorders where the patients often require continuing treatment over very long periods, there is a flat-sum reimbursement regardless of the differences in the prices approved for the individual products.

Determination of the prices for generics

Upon expiration of the patent term **PATENTS** of a medicinal product, one or more manufacturers may submit applications for Manufacturing and Import Approval of generic product. Under the current system, those applications are usually reviewed and given approval in parallel. Similarly, the inclusion on the National Drug Tariff List is done once a year. For the calculation of the reimbursement price of newly introduced generic products three different formulas are applied:

A) With an original product on the market – the price of the first generic product to be introduced is calculated as 80 % of the price of the original product.

B) With an original and two or more generic products on the market - the price of the new generic product to be introduced is calculated as equal to the price of the cheapest marketed generic product.

C) With an original and twenty or more generic products on the market - the price of the new generic product to be introduced is calculated as 80 % to the price of the cheapest generic product, as the firstly introduced generic product is excluded.

The holders of Manufacturing and Import Approval for a generic product received during the period between two annual inclusions in the NHI Drug Tariff List may apply for inclusion. Since year 2000, the MHLW requires all applicants to submit in addition to the application for reimbursement, a list describing their previous generic products – including those given reimbursement price, the withdrawn products and the products still on the market. After reviewing the list, the companies found to have high percentage of discontinued products (regardless of the reasons) are contacted and encourage making a voluntarily withdrawal of their applications.

The base of this approached is both economical and political. Under the current rules for pricing the generic products, the later the product is applied for reimbursement price the lower is the approved tariff. The periodic revision **PRICE REVISIONS** of the prices of generic products is done biannually, but applying different calculation method – the so called "GE rule". The prices of the first generics to an original product are initially relatively higher, but as a result of the periodic re-pricing steadily decrease. Therefore, the generic products, which are late entries, are likely to receive much lower reimbursement prices, thus prompting the applicant either to withdraw the application or to apply for de-listing immediately after the price approval. In fact, some of the manufacturers having both the Manufacturing and Import Approval and reimbursement price never actually produces and ships the product.

The above is a situation what the authorities are actively trying to prevent. Even an application for de-listing from the National Drug Tariff List is filled the same day as the publication in the Official Gazette, the generic product will remain listed for one additional year until next year's annual revision. Under such circumstances, if a medical institution is trying to curb the expenditures by using generics, the prescribing physician or pharmacist might find that a given product is neither available in the institution nor suppliable by the wholesalers, because of not being manufactured. As a result the credibility of generics is damaged and this is one of the reason explaining the tendency among Japanese practitioners to prescribe mostly brand-name pharmaceuticals, thus undermining the Government efforts to use more generics in order to sustain the healthcare expenses.

National Drug Tariff List

The medicinal products listed in the National Drug Tariff List are listed by their trade name (regardless whether there might be other products with identical contents and approval standards) and the purchase price – also called a tariff rate, is set up per standard unit – e.g. per a tablet or capsule. Thus the National Drug Tariff List can be viewed both as a

- Price list – used as a reference in the calculation of the treatment costs in the medical institutions, and as a
- Product list – for the medical institutions operating under the

Japanese health insurance system the National Drug Tariff List serves as a list of products approved to be used under the coverage of the health insurance.

The drug tariffs approved by the Minister of Health, Labour and Welfare are made public in several different ways:

- ✓ By notifying the applicant for reimbursement listing by handing the written decision
- ✓ By publishing the approved price in the Official Gazette
- ✓ By periodically publishing the List of Purchase Prices (NHI Drug Tariff) for Medicinal products to be used – in a form of Attached Table (see for example MHW Notification No. 30 of March, 1998)
- ✓ Listing of the reimbursement prices by including the names and specifications of the products in MHLW Notifications for newly approved products or for revisions of already established prices
- ✓ From commercial sources – such as the "Directory of Pharmaceuticals used for Medical Services Covered by Health Insurance" (*Hoken-yaku Jiten*), published annually and grouping all products into several categories – such as for internal use, for external use, injectables and dental products.

The National Drug Tariff List is also known in English -as Pharmaceutical Tariff Table, NHI Price List, NHI Reimbursement Price List, NHI Drug Price Tariff as different translations from *Yakka Kijun* in Japanese.

Periodical re-pricing of marketed medicinal products

The prices for the medicinal products with reimbursement **PRICING** are subjected to periodical revisions **PRICE REVISIONS** .

Format and content of the application for reimbursement

In Japan, there is no "pricing dossier" in the format used in other regulatory regions. Initially, the application for reimbursement contains an Application Form and certain background information. The review for approval is proceeded under a designated procedure **PROCEDURE FOR PRICE APPROVAL** with the main stages at the Economic Affairs Division of the Health Policy Bureau, the Medical Economics Division of the Health Insurance Bureau of MHLW, the Drug Pricing Organisation, **DRUG PRICING ORGANISATION** the Central Social Insurance Medical Council (*Chuikyo*), and the Minister of Health, Labour and Welfare. Documents from each step – such as evaluation reports, opinions requested by the Medical Economics Division from various academic institutions, notifications to and objections (appeals) from the applicant are attached to the original documentation.

Where to send the application

If the holder of the Manufacturing and Import Approval decides to apply for reimbursement, an Application Form should be submitted to the Federation of Pharmaceutical Manufacturers Associations in Japan, FPMAJ, headquartered in Tokyo. The application for an individual product or group of products – such as generics, are collected and forwarded to the Economic Affairs Division of the Health Policy Bureau. Further the application is processed by the Medical Economics Division of the Health Insurance Bureau of MHLW, the Drug Pricing Organisation **DRUG PRICING ORGANISATION** and Chuikyo before authorisation of the new price by the Minister of Health, Labour and Welfare.

REIMBURSEMENT

The reimbursement system in Japan is based on a universal health insurance for all residents, no upper limit for medical expenses, and reimbursement of the pharmaceutical expenses based on a "fee-for-services system." Therefore, medical institutions are paid for the pharmaceutical expenses in accordance with the amounts actually used. The reimbursement practice in Japan also is closely linked with process of pricing and the distribution system for medicinal products.

Pricing and re-pricing

The medicinal products eligible for reimbursement are given a reimbursement price **PRICING** and entered in to the Health Insurance Drug Tariff List. Periodically, the prices of the reimbursed medicines are revised **PRICE REVISIONS** and the newly updated prices are re-entered into the Tariff List.

National Health Insurance Drug Tariff List

The medicinal products listed in the National Drug Tariff List are listed by their trade name (regardless whether there might be other products with identical contents and approval standards) and the purchase price – also called a tariff rate, is set up per standard unit – e.g. per a tablet or capsule. Thus the National Drug Tariff List can be viewed both as a

- Price list – used as a reference in the calculation of the treatment costs in the medical institutions, and as
- Product list – for the medical institutions operating under the Japanese health insurance system the National Drug Tariff List serves as a list of products approved to be used under the coverage of the health insurance.

The drug tariffs approved by the Minister of Health, Labour and Welfare are made public in several different ways:

- ✓ By notifying the applicant for reimbursement listing by handing the written decision
- ✓ By publishing the set up price in the Official Gazette
- ✓ By periodically publishing the List of Purchase Prices (NHI Drug Tariff) for Medicinal products to be used – in a form of Attached Table (see for example MHW Notification No. 30 of March, 1998)
- ✓ Listing of the reimbursement prices by including the names and specifications of the products in MHLW Notifications for newly approved products or for revisions of already established prices
- ✓ From commercial sources – such as the "Directory of Pharmaceuticals used for Medical Services Covered by Health Insurance" (*Hoken-yaku Jiten*), published annually and grouping all products into several categories – such as for internal use, for external use, injectables and dental products.

The National Drug Tariff List is also known in English -as Pharmaceutical Tariff Table, NHI Price List, NHI Reimbursement Price List, NHI Drug Price Tariff as different translations from *Yakka Kijun* in Japanese.

Distribution

Although with sales deregulations in 1999 the number and the diversity of the sales channels increased significantly, the distribution chain from manufacturers through wholesalers to the end purchasers of the prescription medicinal products remains relatively unchanged.

Historically, the origin of the wholesalers in Japan is rooted in the practice of

peddling (external sales) of the pharmacies. Currently, there are about 1,000 registered wholesalers falling into several categories:

- Primary, secondary and tertiary wholesalers – in dependence on whether they purchase the merchandise directly from the manufacturers (primary wholesalers) or from other wholesalers;

- Wholesalers with business tie-ups with large pharmaceutical manufacturers – the largest wholesalers in Japan are affiliated with one of the four major pharmaceutical companies: Takeda, Shionogi, Tanabe and Daiichi. Those wholesalers are part of distribution and sales networks dealing exclusively with the products of the patron manufacturers;

- Manufacturers direct wholesale channels – distribution outlets formed either by spin off of the sales departments of the pharma companies (as separated companies), or small (mainly local) wholesalers sustained by investments made by the pharmaceutical companies;

- Miscellaneous wholesalers – relative smaller and newer wholesalers using direct mail, cash-and-carry system and other non-traditional sales and distribution methods.

Most of the wholesalers are associated in regional wholesalers associations and collectively members of the Federation of Japan Pharmaceutical Wholesalers Associations, FJPWA (*Nihon Iyakuhin Oroshigyo Rengokai* or *Oroshiren*). Although the nominal number of registered wholesalers is high, the number of the companies with actual presence in the market is much lower. According to the FJPWA, the number of wholesalers in year 2000 has fallen to less then 200, as the first 50 (in term of sales volumes) are responsible for 89% of the transactions.

The pharmaceutical wholesalers have also expanded rage of responsibilities – including monitoring for adverse events and providing stable supply of medicinal products. The current system for post-marketing surveillance is scheduled to be overhauled from October 1, 2001 and all wholesalers to be engaged in the process of gathering AE information, and according to the Japan Society of Wholesalers

Pharmacists - with an increase role of the in-house pharmacists.

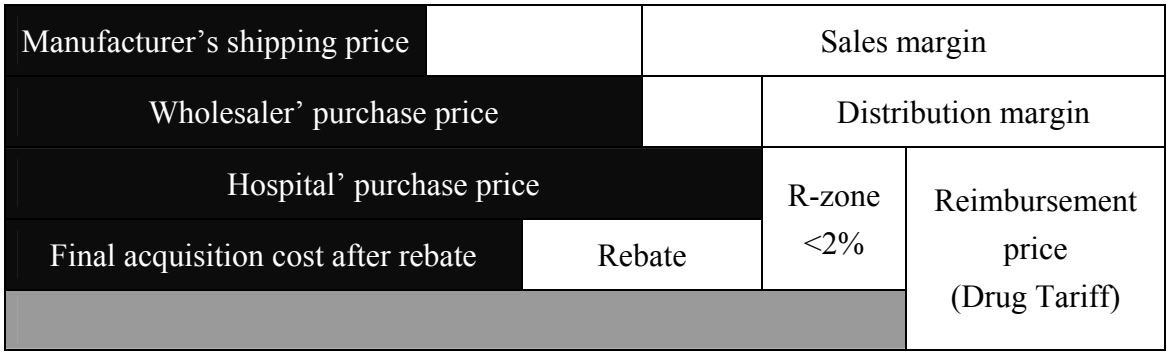
From the other hand, having a key position in the supply chain of medicinal products, wholesalers are constantly monitored by the Japan Fair Trade Commission as the main focus is on the sales at unfair market prices, unjustifiable rebates, formation of cartels to fix the prices for certain categories products, and so forth. The activities of wholesalers are also closely monitored by prefectural governments – who are issuing both the wholesalers' business licences (Kyoka) and various guidelines – such as the "Wholesaler Business Operation Guidelines" prepared by the Tokyo Metropolitan Government in June 2000.

While in the past the only end-purchasers of the wholesalers were the various medical institutions, at present due to the increase of the *Bungyo* practice to over 40 % of all prescriptions, the licensed pharmacies emerged as important customer as well.

Reimbursement

The present players and the system for distribution and reimbursement in Japan is schematically illustrated below:

Diagram



The diagram follows the supply chain for medicinal products from the manufacturer to the end customer – a medical institution or a pharmacy. This diagram refers only to medicinal products already having a reimbursement price and included in the Drug Tariff List (see below). All other prices shown, regardless of the ratio between

each of them remain below the reimbursement price. With some seldom exceptions, where the transactions prices may exceed the reimbursement price, all participants – vendors, wholesalers and purchasers are avoiding trading prices above the drug tariff.

The manufacturer ships the product to the wholesaler at certain price called invoice price, as the difference with the wholesaler's purchase price represents the sales margin for the manufacturer. Then the wholesaler sells the product to the customer (e.g. a hospital) at certain price. The price or in fact – the discount rate, is negotiated in advance and usually once a year. The difference between the wholesaler's purchase price and the hospital's purchase price represents the distribution margin for the wholesaler.

The end customers – medical institutions and the pharmacies are not only reimbursed for the prescribed and dispensed medicines, but they also may have a profit margin. The profit margin derives from the difference between the hospital's purchase price and the reimbursement price. This margin is called "R-zone" (from Reasonable) and at present is not permitted to exceed 2 %. The R-zone is defined also as allowable margin between a medical facility's acquisition cost and the reimbursement price.

Yakkasa

The margin which medical institution may have as a differential between the actual (final) cost for acquisition of a medicinal product (after the discount given by the wholesaler and eventually rebates) and amount of funds they receive as reimbursement is also known in Japanese as *yakkasa*. It has been a traditionally a sources of income for the medical facilities. Beside the R-zone differential, rebates from the manufacturer and/or the wholesaler may add up to the yakkasa. According to some estimations[1] between 70 and 80 % of all prescription medicines are moved down the manufacturer-wholesaler-hospital chain and thus subjected to the R-zone. The yakkasa profit was estimated in 1995 to be over 10 billion US $. This has led to the phenomenon of over-prescription practice, which especially among the individual practitioners (proprietors of small clinics combined with dispensaries).

[1] Source: Japan Medical Association (JMA)

Bungyo

However, the control over the R-zone significantly undercut it as a profit source, thus stimulating the Bungyo practice - recently reported to already exceed 40 %. In addition to the lack of the previous incentive for over prescribing, the separation of the prescribing from the distribution practice has been further encouraged by governmental measures such as increase of the consulting and prescribing fees for doctors.

R-zone (price adjustment ratio)

The size of the R-zone is one of the critical elements for the periodical price revisions **PRICE REVISIONS** For the last ten years the R-zone has shrunk from 15 % in 1991 to 2 % for long-listed products and 5 % to all others in 1998 and ultimately – to 2 % for all reimbursed products in 2000, when it was renamed "price adjustment ratio".

The negotiations between the end-purchaser and the wholesaler are important part of the Japanese distribution system for medicinal products, which was seriously challenged in year 2000 with the higher cut across all reimbursement prices and the introduction of the price adjustment ratio of 2 %. The price revision **PRICE REVISIONS** carried out in April 2000 resulted in prolonged negotiations with the hospitals and increase of the practice to supply medicinal products at provisional prices, since many hospitals kept insisting on receiving the same range of *yakkasa* as before.

It should be pointed that presently (May 2001) the future of the R-zone is under a debate. The representatives of the wholesalers (FJPWA) argue that the current level is too low and uniform to take into consideration the variety of expenditures associated with distribution (package size, distance to the purchaser, payment methods, etc.), and that supply of medicinal products contain not only commercial, but social component.

The representatives of the medical professionals insist of return to higher R-zone at about 10 % including current 2 % price-adjustment ratio plus 5 % national consumption tax and 3 % as a technical and management fees.

Although the manufacturers are not involved in the dealings with the medical

institutions, they are primary interested in the determination of the reimbursement prices and their subsequent revisions. In contrast to the other parties involved, the representatives of the industry[2] have expressed both satisfaction of the stabilisation of the market due to the elimination of the excessive *yakkasa* and disagreement with the NHI price determination methods.

For those and other reasons, as reported in November 2000, the Health Insurance Bureau of the MHW (now - Health Insurance Bureau of MHLW) is currently envisioning different variants for the future of R-zone in the wake of the reforms in 2002, including its abolishment.

Payment of the reimbursement amounts

From the Diagram (see above) is obvious that due to the complexity of the distribution system, the financial relations between all participants may also be complicated. The manufacturers received the payments for their merchandise from the wholesalers as the amount and terms of payments are prearranged. From the other side, the medical institutions compile and submit documentations to either society- managed health insurance programs or to the National Health Insurance program, in which case the reimbursement reports are to be submitted to the respective prefectural governments.

[2] FPMAJ Presentation to Chuikyo, November 22, 2000.

PROCEDURE FOR PRICE APPROVAL

The procedure for price approval of a newly approved medicinal product **PRICING** differ from the procedure for periodical revision of the price of a product already included in the National Tariff List However, in both cases the following main steps are included:

Flowchart

Initial application or inclusion in the list for re-pricing

⇓

of the Health Policy Bureau

⇓

Medical Economics Division of the Health Insurance Bureau

⇓

Drug Pricing Organisation **DRUG PRICING ORGANISATION**

⇓

Medical and Insurance Welfare Council (*Chuikyo*)

⇓

Minister of Health, Labour and Welfare

⇓

Official Gazette

The timeframe of the procedure for approval of the new product is set up to be concluded for about 60 days, but no longer than 90 days after the date of the granting the Manufacturing and Import Approval.

During the review and approval process the representative(s) of the applicant may appear in person at the hearings in the Economic Affairs Division of MHLW and at the meetings with the Drug Pricing Organisation **DRUG PRICING**

ORGANISATION , and may submit objections or additional information in writing. If the applicant is dissatisfied with the proposed price, the application can be withdrawn, or alternatively applied for delisting immediately after publications in the Official gazette.

PRICE REVISIONS

The prices for the medicinal products with reimbursement **PRICING** are subjected to periodical revisions. After application according to the procedure for price approval **PROCEDURE FOR PRICE APPROVAL** and the determination of the reimbursement price all transactions including the actual reimbursement **REIMBURSEMENT** should be conducted within its limits. Those transactions involve moving the product through the supply chain from the manufacturer and wholesaler to the medical institution, and the payments – in reverse order starting from the insurer.

Since there are no governmental regulations concerning any other then the reimbursement price, during the period of trading with the medicinal product following the determination of its reimbursement price, the actual trading prices – the manufacturer's shipping price, the wholesaler's purchase price, etc. may vary (see Diagram **REIMBURSEMENT**), and the market size for the product may fluctuate as well. In parallel, the principal indications, efficacy and safety profile, dosage and mode of use of the product may also be modified. Therefore the reimbursement prices are reviewed and actualised periodically.

Price revision system overview

The system for price revision has been established n 1991 upon a recommendation by the Central Social Insurance Medical Council (*Chuikyo*). The price revisions are carried periodically, as until now there have been six rounds of price revisions – in 1992, 1994, 1996, 1997, 1998 and 2000, respectively. In principle the price revisions are carried out biannually – in even year, except in 1997 when an extraordinary revision was made to reflect the introduction of the national consumption tax of 5 %. Each price revision consists of two consequent steps – a comprehensive survey of the actual market prices of the reimbursed medicinal products and based on the results of the survey revision of the prices.

Survey of the actual market prices

The survey of the actual price used in the transactions involving reimbursed medicinal products is conducted in the year preceding the year when prices are to be revised – i.e. in 1991, 1993, 1995, 1996, 1997 and 1999. At the current fiscal 2001 year a survey is scheduled and the results shall be used for the revision of prices in 2002. For the purpose of the survey the following method is used (exemplified by the data from the last survey carried out in 1999). A range of selected responders – about 3,400 sellers, all first-class wholesalers and around 2,800 purchasers (medical institutions and pharmacies) was queried. The selection of the responders was done based on the random sampling. The subject of the query was the sales and prices registered during a specified month. For the first three surveys the specified month was June and for the last three, including the survey in 1999 – September. The data of these market snapshots are analysed and the range - within which the prices actually used for each of the reimbursement product, including in different regions of the country, is determined. In addition – survey and analysis are carried out to compare the changes in prices chronologically. The results are the base for the comparison and price revision – called also price adjustment.

Revision of the reimbursement prices

The prices may be revised downward, upward or to remain unchanged after the revision. A summary of the latest revision of the National Drug Tariff List **PRICING** prices is shown in the table below.

Table. Price revision in

Type of revision	Number of products	Percent
Prices revised **downward**	8,935	79.2
Prices revised **unchanged**	2,291	20.3
Prices revised **upward**	61	0.5
Total	11,287	100.0

It is obvious that the prices of the most of the products have been reduced, the percentage of the products which prices remain unchanged is relatively small, while the number of products with increased price is negligible.

Form the other side it was reported that the average price cut was 7 % and varying depending on the therapeutic category. Regarding the breakdown per mode of administration the number of brands was as follow: 6,209 oral, 3,166 injectables, 1,870 topical and 42 dental products. Generally, the prices of injectables were reduced at higher rate compared to the cut for oral products, as the price cut for contrast media was the highest at 9.6 %. Among the orally administered products the highest price reduction was of the synthetic antibacterial agents (8.7 %) and the lowest – 5.3 % for antiarrhythmic medicines.

The reason for the predominately reduction of the prices is the continuous discounting of the prices as a result of negotiations between the wholesalers and the purchasers (medical institutions and pharmacies). The medical institutions demand as big as possible discount for the purchase prices from the wholesalers in order to increase the price differential with the reimbursement price, and thus their income. However, at the regular surveys it will be found that the average price used in the transactions falls below the R-zone and at the price revision the price of the products will be revised downward. Following the reduction, the medical institution will start to negotiate again prices lower than the official drug tariff, and in turn this will lead to another reduction at the following year. Although in a theory, the prices of the medicinal products can be kept unchanged for years, under the market conditions the

described process drives the prices to a lower level every year.

Additionally, the prices can be affected adversely by the introduction of generics **PRICING** or by unexpected fluctuations in sales volumes.

Reduction of the R-zone

The *yakkasa* **REIMBURSEMENT** – the differential between the actual cost incurred by the medical institutions for the acquisition of medicinal products and the reimbursement amount they received under the health insurance system has been for years a source of significant income for the medical institutions, as been in the 1970s as high as 23 %. With the goals to simultaneously eradicate the practice of over-prescribing and to curb the medical expenditure the R-zone (Reasonable zone) was introduced in 1992 and initially it was set up at 15 %. As shown in the table below, in following revisions the R-zone was reduced to the current level of 2 %.

Table. Reduction of R-zone

Year	**R-zone (%)**	
	Long-listed products	**All others**
1992	15	
1994	13	
1996	11	
1997	8	10
1998	2	5
2000	2	

Although now it is acknowledged that steady reduction of the R-zone has resulted in the eradication of the *yakkasa* practice, its future – including the value and involvement in the reimbursement mechanisms **REIMBURSEMENT** are under discussion, and possibly change in year 2002.

Price revision system details

Both the system for pricing **PRICING** of the medicinal products and the periodical re-pricing have been revised repeatedly with the aim of their improving, eliminating the *yakkasa* practice and reducing the health insurance burden. Regarding the critical matter of the determination of the initial and revised prices of the individual products, various methods (formulas) have been applied, and successively changed in the amendments in 1982, 1987 and 1991. In brief, the historically first 90 % bulk-line system was modified in 1980s and completely replaced in 1991 with the new formula proposed by Chuikyo translated in English as “weighed average pricing formula” (or "the weighted average price plus fixed allowance system”).

The 90 % bulk-line system

After collecting the data from the actual dealings in the market for a given products, the lowest rage is determined and the tariff rate price is calculated by adding 90 % to the lowest price. The 90% bulk-line system was the core of the pricing method I (see below) – the most commonly used method for calculation of the prices of the medicinal products. The pricing method I is used for the calculation of the prices of most of the products included in the National Drug Tariff List based on the 90 % bulk-line system. From 1982 the 90% bulk-line system was deployed in two different variants. If the actual prices of a given product are spread across a wide range, the bulk-line system is applied in its “90 %” variant. In the cases when the actual prices of a given product are spread across a narrower range, the bulk-line system is applied in its “81 %” variant. The 90 % bulk system was used with modifications from 1982 and 1987 until 1991, when its use was discontinued.

Weighted average price plus fixed allowance formula

The weighed average pricing formula is based on the results of the surveys of the actual market prices (see above) where the relevant data are processed by the calculating weighted means of sales prices of all existing package sizes by brand sold in the month of observation. The weighed average (WA) price along with the reimbursement price (ReP) by the time of the revision and the value of the R-zone are

used in the following formula:

$$\text{New Price} = \{WA + \frac{WA \times Tax}{100}\} + \frac{ReP \times R\text{-zone}}{100}$$

Legend:

WA - weighed average

Tax – Japanese national consumption tax set up at rate of 5 % from 1997

ReP – reimbursement price – the price of the products as listed in the National Drug Tariff List

R-zone – at present set up at 2 % level

Example:

Let assume that a certain Product A has an official reimbursement price of 100 Yen per tablet, and the weighed average price found after the survey of the market prices is 80 Yen per tablet. Using the cited formula:

$$\text{New Price} = \{80 + \frac{80 \times 5}{100}\} + \frac{100 \times 2}{100} = 86$$

it would be calculated that the new price for reimbursement of the Product A after the revision should be 86 Yen.

The above formula is used for calculation of the new (revised) prices for products sold in relatively large quantities. It is expected that the newly derived price should be lower than the existing prices – both the market prices and the official reimbursement price. However, if as a result of the calculation the new price appears to be higher than the existing reimbursement price, the price of the products after the revision either remains unchanged or it is modified using different methods and/or considerations.

Pricing methods I, II, III and IV

At present four different methods are used to calculate the prices of medicinal products included in the National Drug Tariff List, depending on the sales volumes type of the products and other factors.

- Pricing method I

This is the method where the weighted average price plus fixed allowance formula is used with current R-zone (price adjustment ratio) fixed ate 2 %.

- Pricing method II

The pricing method II is applied for products sold in relatively smaller amounts – defined as product on a low market demand and thus limited sales. For those product the above system is not applicable and their prices are fixed by using an index for comparison with similar products.

- Pricing method III

The pricing method III is applied for calculation of the tariff rate on the basis of the actual prices in the market for previous half year or longer period.

- Pricing method IV

The pricing method IV is applied for calculation of the tariff rates of products other than those in the categories products eligible for the pricing methods I, II and III. It is consider that the products which prices are calculated using pricing method IV are neither profitable nor sold in large volumes.

Typical example of this type of product is the category of the orphan medicinal

products. By definition those are products for treatment of conditions where the actual number of patients and newly diagnosed cases could be quite low. Moreover as shown in the list of the approved orphan medicines for a number of indications, there are more than one approved product, what results in lower sales for each of the these similar products. The prices of such products tend to be revised upward.

Price revision for generics

The prices **PRICING** for generic products are determined and subsequently revised under the similar methods as the brand products. Under the current rules for pricing the generic products, the later the product is applied for reimbursement price the lower is the approved tariff. The periodic revision of the prices of generic products is done biannually, but applying different calculation method – the so called "GE rule". The prices of the first generics to an original product are initially relatively higher, but as a result of the periodic re-pricing steadily decrease. Therefore, the generic products, which are late entries, are likely to receive much lower reimbursement prices, thus prompting the applicant either to withdraw the application or to apply for de-listing immediately after the price approval.

During the recent and the ongoing debates on the prices and pricing of the covered medicinal products, and on the health insurance system in general, a number of organisation have made various proposals for introduction of different pricing/re-pricing systems – including so called Japanese style reference price system, free-pricing system and so forth. It is expected that the price revision system shall be further modified along with the healthcare reform planned by the Government for 2002.