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Comparison of pharmaceutical policies to stimulate use of generics in Japan and Sweden

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Abstract
Objectives: Among OECD countries, the proportion of total expenditure on health spent on pharmaceuticals is highest in Japan, 20%. In Sweden, the corresponding proportion is 13%. Swedish pharmaceutical expenditures increased dramatically in the 1990s and policy changes were introduced to curb this. Both countries have introduced policy changes to increase cost containment. This study aims to compare the pharmaceutical policies regarding generic medicines in Japan and Sweden.
Methods: Information on pharmaceutical policies was collected. We compared pharmaceutical policies according to the 4E (Education, Engineering, Economics, and Enforcement) component framework developed to describe the differences in policies.
Results and conclusions: In Sweden, there were several organizational and managerial interventions within the Engineering class. Japan had several positive incentives for health care actors in the Economics category. The Enforcement category had a stronger legal component in Sweden compared to Japan. The Swedish policies were mainly directed towards prescribing and dispensing whereas the Japanese addressed several stakeholders to promote use of generic drugs. The countries were similar with respect to the Education category. Within the Enforcement component the Swedish policies were legally enforced whereas the Japanese to large extent were recommendations.

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Introduction

Maintaining resources spent on health care and striving for maximizing health benefits is important in most health systems. In the last decades, the health expenditure has increased in developed countries as has the pharmaceutical expenditure. An aging population and new drug development have been reported to contribute to an increase in the proportion of health care expenditure that pharmaceuticals constitute. In many countries, governments, non-government organizations and private insurers have sought to develop systems for cost-containment and a sustainable development [1-5]. Both the supply and the demand-side of the pharmaceutical market encompass several stakeholders. These include residents (patients) and health care providers on the demand-side, pharmaceutical manufacturers on the supply-side. It also includes governments that strive to balance the desire for optimal health care and economic growth [6].

According to the Organization for Economic Cooperation and Development (OECD) data the total expenditure on health per capita in Germany was 2671 USD in the year 2000, and 4349 USD in 2010, respectively. The corresponding figures were 1833 USD in 2000 and 3433 USD in 2010 for the United Kingdom (UK), and 2283 USD and 3758 USD, respectively, for Sweden [7]. Pharmaceutical expenditure accounted for between 11% and 14% of total health expenditure in these countries [7]. Despite that the total expenditure of health per capita in Japan was at the same level as European countries (3213 USD in 2010), pharmaceutical expenditure constituted 20% of total expenditure on health in 2010 [7] (1EUR=1.03USD in 2000, 1EUR=1.39USD in 2010). It is the highest among the OECD countries [7]. The increasing use of generic drugs seems effective to slow down growth in expenditure in European countries [6]. Generic substitution is applied in many European countries in different forms. In United Kingdom (UK) hospital settings, generic substitution by pharmacists is standard practice alongside prescribing by the International Nonproprietary Name [8]. In France, generic substitution is applied in pharmacies and estimates suggest saving of approximately 1 billion euro per year by dispensing of generics [9]. The constitution of the health systems differ to great extent between countries. Some countries have mainly publicly (national) funded health care (e.g. Finland [10], UK [8], Sweden [11], Norway [12], Canada [13] whereas others have an insurance based health care system with either private or more or less public health insurances (e.g. the US, Germany [6], Japan [14].

Baseline data with general information on the two countries describing the population and the health care system is presented in Table1. The Japanese health care system is based on social insurance whereas the Swedish is based on tax funding. Hospital admissions in both outpatient and inpatient care were 3.9 and 3.5 times more common in Japan compared to Sweden. The length of acute care hospital stay was also longer in Japan than in Sweden (18.2 days vs. 4.5 days, respectively). The share of generic drugs by volume in Sweden was 49%, whereas in Japan it was 23%. Pharmacy mark-up in Japan was unregulated. The average mark-up rate of reimbursed products was 8.4%. In Sweden, selling price and mark-ups are regulated by the Dental and Pharmaceutical Benefits Agency, TLV. Three different margin schemes are applied, depending on whether the product is subject to generic competition or not. Margins are regressive with increasing price on four levels. The three margin schemes all include a proportional component and a fixed add-on. Since the basis of the types systems are very different, this is a good starting point for a comparison of the use of generic medicines where the two systems can learn from each other. This may be useful for decision-makers contributing to increased understanding on how different measures work in different settings. In this paper we chose to compare Japan and Sweden since these countries have substantially different systems and the development of pharmaceutical expenditure has been very different in the last decades.

In Japan, cost control is provided by the nationally uniform fee schedule for reimbursement. The fee schedule controls the money flowing from all insurance plans to almost all providers for about 3500 insurers [15]. The Japanese government has introduced pharmaceutical policies striving to increase cost-containment. An economic incentive where a hospital or clinic could receive an extra 20 JPY(1 EUR=115.8 JPY in 2002) for each prescription containing at least one generic product was introduced in 2002 [16]. In 2003, the fixed fee payment system called DPC/PDPS was introduced at major acute-hospitals to stimulate these hospitals to increase usage of generic drugs and thereby contributing to cost savings [17,18]. In June 2007, the Ministry of Health, Labour and Welfare (MHLW) published a "New vision for the pharmaceutical industry" aiming at a wealthy country which can "supply citizens with safe and high-quality pharmaceutical products meeting medical needs as early as possible at reasonable prices", and decided to revise the drug pricing rules after debating on the board of the Central Social Medical Insurance Council (Chuikyo) [19]. It was under debate at the end of the financial year 2012 (FY2012). Additionally in 2007, the Cabinet Office's Council on Economic and Fiscal Policy stated that the quantity-based share of generic pharmaceuticals should be increased to 30% by FY 2012 [16,20]. The "Action Program for the Promotion of the Safe Use of Generic Drugs" was formulated as a response to suggestions from healthcare professionals, to promote more confident use of generic drugs by patients and medical personnel [21]. The program included five subjects; (1) stable supply of drugs, (2) quality assurance of drugs, (3) appropriate provision of information by generic manufacturers, (4) creation of the appropriate environment for promotion of use of generic drugs, and (5) matters related to the health insurance system. The first three subjects targeted the supply-side and the others the demand-side. The share of generics has increased since 2002, when the share was 12.2-22.8% in 2012. However, a large part of the gain occurred between 2002 and 2003, and the increase during 2003-2009 has been 0.63 percentage points per year on average [16].

Between 1990 and 2000, the total expenditure for pharmaceuticals more than doubled in Sweden [22]. An increased volume of pharmaceuticals sold, a shift towards use of more expensive drugs, and introduction of new pharmaceuticals contributed to this [22]. Two major pharmaceutical benefit reforms that aimed to cut the escalating pharmaceutical expenditures and promote rational drug use were implemented in 1997 and 2002. In 1997 a new construction of the pharmaceutical benefits scheme (PBS) and an obligation for