MEMORANDUM CONCERNING THE PHARMACEUTICAL SECTOR INQUIRY

The sector inquiry is fundamentally concerned with the analysis of the structure and operation of the market at the supplier level. The starting section of the examination closely follows the sector inquiry of the European Commission. For the following section, interviews were conducted with General Directorate for Pharmaceuticals and Pharmacies (renamed Turkish Pharmaceuticals and Medical Devices Institution), Social Security Institution (SGK), Association of Research-Based Pharmaceutical Companies, Pharmaceutical and Chemical Industry Employers' Union, Turkish Pharmaceutical Industry Association, Pharmaceutical Distributers Association and Bidder Pharmaceutical Distributers Association in order to gather information on the Turkish pharmaceuticals market, with detailed information collected from the aforementioned institutions, organizations and associations. Also, the opinion of the Turkish Medical Association and Turkish Pharmacists' Association was requested, as well. In addition, information was also requested from IMS, which keeps comprehensive statistical data concerning the pharmaceutical sector, and IMS sent a detailed data set at the firm, active ingredient and pharmaceutical level to the Competition Authority. Lastly, the information gathering process was concluded with a survey aimed at the 50 top-ranking pharmaceutical companies according to the IMS TL sales data. The survey requested information-including the information for other pharmaceutical companies in the same group-from the participants under many headings such as their operations and products; their turnovers, R&D expenditures and promotion expenditures; patents they hold and patent suits they are involved in. The survey was completed in the first half of the year 2012.

In the sector inquiry report, observations concerning existing problems and suggestions on the solutions for these problems were organized under four headings of legislation, with a perspective to improve price competition at the suppliers level. Within this framework, priority was given to addressing licensing, pricing and reimbursement stages, which are the fundamental regulations specific to the sector and which, at the same time, comprise the long administrative process before the pharmaceuticals are put on the market. The following section discusses patent applications which are not specific to the sector but which have significant effects on

competition. After that subjects which demonstrate the operation of the market such as R&D and promotion activities, entry into market and competition from generic products are evaluated.

There are failures concerning price competition in the pharmaceuticals sector. First of all, final consumer, who is expected to be the most price-sensitive actor on the demand side in other sectors is not sensitive to the price in the pharmaceuticals market or has low price-sensitivity. This is because consumers have limited contribution to pharmaceutical expenses. In this case, in order to affect demand, firms tend towards demonstrations to doctors and promotion/campaigns for pharmacists instead of price competition. Doctors are final decision-makers, however they are not well-informed on prices and therefore are not sensitive to them. Pharmacies, on the other hand, naturally act in line with profitability and prefer those products which offer them the best terms of purchase when they exercise their discretion rights within the framework of the equivalent drug practice.

The real goal of promotion activities is to inform healthcare professional about the properties of the products. However, it is also known that such activities may create brand loyalty in doctors and form barriers to entry to the market. Also, generic drug firms, whose strongest weapon is to implement lower prices, may act like brand companies and incur high promotion expenditures. Therefore, in terms of both brand and generic pharmaceutical firms, the effects of price competition are limited and resources that may be directed to this area are utilized inefficiently.

Another failure in terms of price competition is that, where a competitive structure can not be established at the retail sales level, a significant portion of the gains originating from competition at the supplier level stay limited to the distribution level in the form of favorable purchase conditions (such as surplus goods and discounts). Such gains are not passed on to patients as access to the pharmaceuticals with better conditions or to the State as a decrease in pharmaceutical expenses. Consequently, it is clear that ideal competitive conditions does not exist in a structure which functions on the basis of terms of sales and whose target not final consumers or the State but the pharmacies.

In the sector inquiry report, fundamental regulations as well as patent applications, which are not sector-specific but have significant effects on competition in the market were assessed, following which the indicators on the functioning of the market were examined. The aforementioned examination is conducted under the headings which are attached great importance in literature. Within this framework, in summary, the ratio of R&D and promotion expenditures to operating expenses and total turnovers as well as the distribution of promotion expenditures to promotions aimed at doctors and pharmacists, the share of biotechnology products in total turnovers, the contents and characteristics of agreements between competitors, the relationships between the firms and pharmaceutical warehouses and their potential effects on the supplier level, the launch timing concerning the licensed and original products of the participant global firms in eight selected developed countries including Turkey, generic drug penetration and launch timing for these drugs have been examined.

The main goal of the sector inquiry is the development of price competition in the pharmaceutical sector at the supplier level. Demand- and supply-side measures and regulations are needed to achieve this goal. Demand-side targets are to increase price sensitivity in consumers, create incentives to prescribe the cheapest drug at the retail sales level, and decrease dependency on prescriptions in terms of equivalent drugs. Supply-side targets, on the other hand, are encouraging and accelerating generic drug entry, facilitating and promoting entry into markets by original products which may reduce treatment costs, ensuring that practices related to public prices are transparent, objective and consistent, and stimulating the diversion of resources to price competition.

As a result, the below-listed policy recommendations are made in line with the goal of improving price competition in the pharmaceutical sector at the suppliers level, in order to ensure that patients access drugs with better terms, pharmaceutical expenditures of the State is sustainable, and resources are utilized in funding new and developed products, treatments and services.

<u>Concerning Turkish Pharmaceuticals and Medical Devices Institution</u>

- rendering pharmacist profit rates graded at all price ranges,

- granting exclusivity to or introducing price premiums for the first generic drug for a certain period,
- providing the necessary coordination to combine all patent information concerning pharmaceuticals applicable in Turkey,
- ensuring market access for non-brand pharmaceuticals;

Concerning the Social Security Institution,

- Providing information to prescription owners concerning co-payment and equivalent drug practices each time they take a prescription and providing general information separately,
- Terminating the practice of collecting co-payments at source from those who receive their salaries from SGK, collecting co-payments directly from those concerned at pharmacies,
- rendering prescription co-payments proportional and adding them to drug co-payments,
- not collecting or applying a discount to co-payments in case the cheapest drug within the equivalent drug group is preferred,
- where a cheaper equivalent is dispensed instead of the one prescribed, if the drug dispensed is not the cheapest drug in the equivalent group, either collecting part of the difference between the drug dispensed and the cheapest drug from the pharmacy or, alternatively, calculating pharmacy discounts at one level higher in case the share of the cheapest drugs does not exceed a certain threshold among equivalent drug sales,
- including active ingredients instead of the name of the drug in prescriptions, provided that this practice is supported by methods to promote the cheapest drug, including measures aimed at pharmacists,
- as an alternative to granting exclusivity to or introducing price premiums for the first generic drug for a certain period, setting the public institution discount for the first generic drug at a lower level,
- allowing firms which plan to launch a new original product in the market to conclude risk sharing agreements with SGK,
- holding more frequent Payment Commission meetings,
- reflecting public price changes towards both directions to the system, provided this is in compliance with legislative provisions,

- when conditions specified in the legislation are met, making swift changes in the payment cap towards either direction,
- frequently updating the payment cap which forms the basis for the equivalent drug practice and making swift changes in the payment cap towards either direction when conditions specified in the legislation are met,
- testing the suitability of the tender method in terms of a certain insured and/or equivalent product group,

Concerning the Competition Authority,

- assessing the agreements between brand and generic drug firms by taking into account those characteristics of the sector which enable multi-market communication.