

Price Strategy Bulletin

Turkey: New Pricing Rules Increase Attractiveness of the EU's Latest Candidate

Introduction

Turkey's profile has been raised by the October 3 decision to formally start the EU accession process (application was originally made back in 1959) but even without this historic development the market is proving increasingly attractive to multinational pharmaceutical companies. The country is huge (72 million population), stable (a majority government rather than an indecisive coalition was elected in 2002) and buoyant (GDP growth was 8.9% in 2004 with inflation down to single digits), having fully recovered from the financial and political crises of the previous two decades.

Retail pharmaceutical sales, at manufacturer prices, were the equivalent of \$4.3 billion in 2004. While this is less than half the value of the Spanish market, for example, Turkish growth – 22% over 2003 - is far higher.

Despite a large domestic generic sector (more than 200 marketing companies), combined sales of the 33 foreign-capitalised members of the Association of Research-Based Pharmaceutical Companies (AiFD) represent 60% of the total market by value and 45% by volume. There are 96 manufacturing facilities in Turkey, of which 12 are foreign-owned. Direct employment by the pharmaceutical industry totals 23,000.

Consumption of medicines per capita was only \$85 in 2004 (compared to \$294 in neighbouring Greece, for example). Part of the reason is a cultural one but a major contributor is the fact that Turkish prices are very low (14.6% lower than the lowest in the EU according to the AiFD) but access to reimbursement is easier and faster than in other CEE countries. Last year, a new pricing decree replaced the former cost-plus system.

Products patents were introduced in 1999 and six-year data exclusivity (from the time of first registration in the EU-25) applied from January 2005. Generic applications filed in Turkey prior to this date were exempt, leading inevitably to a surge in applications to beat the cut-off.

Pricing

Setting and maintaining manufacturer selling prices (MSPs) is the responsibility of the Price Evaluation Commission, a group co-ordinated by the Ministry of Health's Drug and Pharmacy Directorate in Ankara. Though it will have to change with accession, pricing is currently part of the registration process (this was otherwise harmonized to EU requirements in a 2005 Regulation); without a price a marketing authorisation cannot be issued.

The maximum introductory price is the product's lowest MSP found in five reference countries (France, Greece, Italy, Portugal and Spain) plus the country of origin. If the product is not marketed in any of the five, any EU country will do.

Other markets that employ geographic price referencing allow companies to self-declare foreign prices but Turkey is far stricter, requiring independent verification. Industry argued that IMS gave prices net of statutory discounts and not official ex-factory ones. The Ministry's response was to demand that applicants include price certificates from authorities in the reference countries. As these can be difficult to obtain, some companies use public notaries to verify foreign prices provided by their affiliates. Last year there was a well-publicised legal challenge to a multinational after it did not declare to the Ministry a low hospital tender price in Portugal.

When prices of affected products in the reference countries decrease by 5% or more, the Price Commission must be informed within three months to obtain a new price. The Ministry also checks the exchange rate with the euro every quarter and, if a minimum 5% change either way is maintained for more than one month, all Turkish prices are adjusted accordingly. There has been a government proposal to exchange Poland and Hungary for two of the existing five price reference countries, but this is unlikely to go ahead. No major market uses Turkish prices to reference against.

The Turkish lira (TL) was one of the world's lowest value currency units, but from January 2005 it lost six zeros to become the more manageable new lira (YTL).

Table 1- Wholesaler and Pharmacy Margins

That part of the MSP	wholesaler margin (%)	pharmacy margin (%)
< YTL 10	9	25
YTL 10.01-50.00	8	24
YTL 50.01-100.00	7	23
YTL 100.01- 200.00	4	16
>YTL 200	2	10

The changeover did not have any inflationary effect on medicine prices as these were already expressed with four zeros. Packs have to be labelled in both currencies for a transitional period of one year.

Wholesaler and pharmacy margins are based on regressive scales (see table 1). All the country's 22,000 pharmacies are independent, no chains are allowed. Value-added tax applies at 8% on all types of medicines (prior to 2005 it was 18%).

Reimbursement

The state pays 89% of the drugs bill. There are at present three separate health insurance funds (SSK, Emekli Sandigi and Bağ-Kur). Covering half the population, SSK, for private company employees and their dependents, is the largest. The poor unemployed now obtain coverage as green card holders, private insurance is growing, but 8-9% of the population is still outside any system. Next year the plan is to extend statutory cover to the entire population and merge the three funds into one. Observers believe the scheduled start-up date for this, January 1st, will be delayed.

Industry is currently trying to obtain release of the draft common positive list for comment. For now there are two different reimbursement lists – one for SSK, and another for the pension fund for state employees (Emekli Sandigi) and the self-employed (Bağ-Kur). The SSK and Bağ-Kur are run by the Ministry of Labor, while Emekli Sandigi is part of the Ministry of Health. Together with the three insurance funds, the State Planning Organisation and the Treasury, the two ministries are represented on the Reimbursement Commission. This meets monthly.

There is a small negative list (e.g vitamins, herbals and cosmetics), prescribing of certain drugs (e.g, for the treatment of erectile dysfunction) is limited to specialists, and a few other products require a Health Commission report from hospitals before they can be used in the community. All other products are reimbursed, a total of 71% of all registered prescription drugs.

In accordance with the 2004 decree, reference pricing applies to all multisource molecules marketed for less than 20 years. The reimbursement ceiling of each group (by strength/dosage form/ active ingredient) is set at 30% above the price of the cheapest generic, providing this has been marketed for at least five months and has a minimum 1% market share by number of packs sold.

Generics must be priced at launch no higher than 80% of the original. This rule applies to the first generic and to subsequent ones too, so price competition is variable.

Patients who are working are required to co-pay 20% of the reference price plus any excess over this, retired people pay 10%, while patients suffering from a limited range of chronic disorders (e.g epilepsy, diabetes) are exempt from co-payment.

SSK hospitals used to rely on tenders to procure supplies for out-patients as well as in-patients, but the former group now has to collect medication from community pharmacies. The changeover increased costs for SSK and contributions were sought from suppliers as an offset. Manufacturers now have to offer all three funds a 4% discount on reimbursed products that have been marketed in Turkey for less than six years (including NCEs) and an 11% discount on older products (including generics). Pharmacies are also subject to a mandatory discount of 3.5%.

Further P&R Developments?

While Turkey has instituted many recent reforms aimed at making the pricing and reimbursement system more transparent but with an eye on controlling pharmaceutical costs, still further developments may be on the horizon. Earlier this year the World Bank suggested to the Turkish government that to seek further economies on the drugs bill it adopt the Australian system of pharmaceutical pricing and reimbursement. Several

members of the interministerial Reimbursement Commission visited Canberra for a week to investigate. However, while there has been no official comment, it is believed that Commission members were unconvinced of applicability of Australian methods to Turkey.

Strategic Implications

Turkey's size and growth potential, coupled with a reformed and far more transparent P&R system, makes it an increasingly attractive target market for the pharmaceutical industry. Due largely to the new green card holders and the transfer of out-patient dispensing from SSK hospitals to the community, the retail market is expected to expand by no less than 50% this year, to reach \$6.3 billion.

The country might straddle two continents with 85% of the population living on the Asian side, but pharmaceutical companies are increasingly looking to Turkey as a key component in their European strategy, regardless of whether EU entry is 10 or more years ahead.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries. PriceSpective has extensive expertise in analysing the pricing environment and developing price strategies across Europe.

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