

GENERAL ASSESSMENT OF UNLICENSED MEDICINE USAGE IN TURKEY

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OBJECTIVES

Pharmaceuticals can be used in un-approved or unlicensed indications or dosages apart from their licensed use. This is called off-label use. In principle, a drug can be considered to be off label under three conditions: (i) if the approval have not been extended, although evidence of efficacy is available; (ii) if it falls into the so-called 'grey zone' of evidence-based medicine, within which high-level evidence is difficult to reach even for treatments which are likely to be effective and (iii) if the drug is ineffective or at least there is no reason to believe it is effective (Koçkaya et al., 2011).

Off-label use is defined by the Turkish Ministry of Health (MoH) as the use of licensed pharmaceutical products in doses outside of or exceeding the scope of the registered indication and the use of unlicensed medicinal products that are imported for the purpose of individual treatment. Hence, off-label use covers both licensed and unlicensed products (Koçkaya et al., 2012).

The Turkish Medicines and Medical Devices Agency (TMMDA) gives the permission of unlicensed medicine use on patient basis. Authorized wholesalers including Turkish Pharmacists' Association (TPA) can import the drugs based on the TMMDA's permission. These medicines are reimbursed by the Social Security Institution (SSI), the main reimbursement agency in Turkey. Until 2014, , pharmaceuticals under this status could only be imported by the Turkish Pharmacists' Association (TPA) when wholesalers were also authorized.

This study aims to understand the trends in unlicensed medicine consumption between 2011 and 2013 when the TPA was the only authorized supplier.

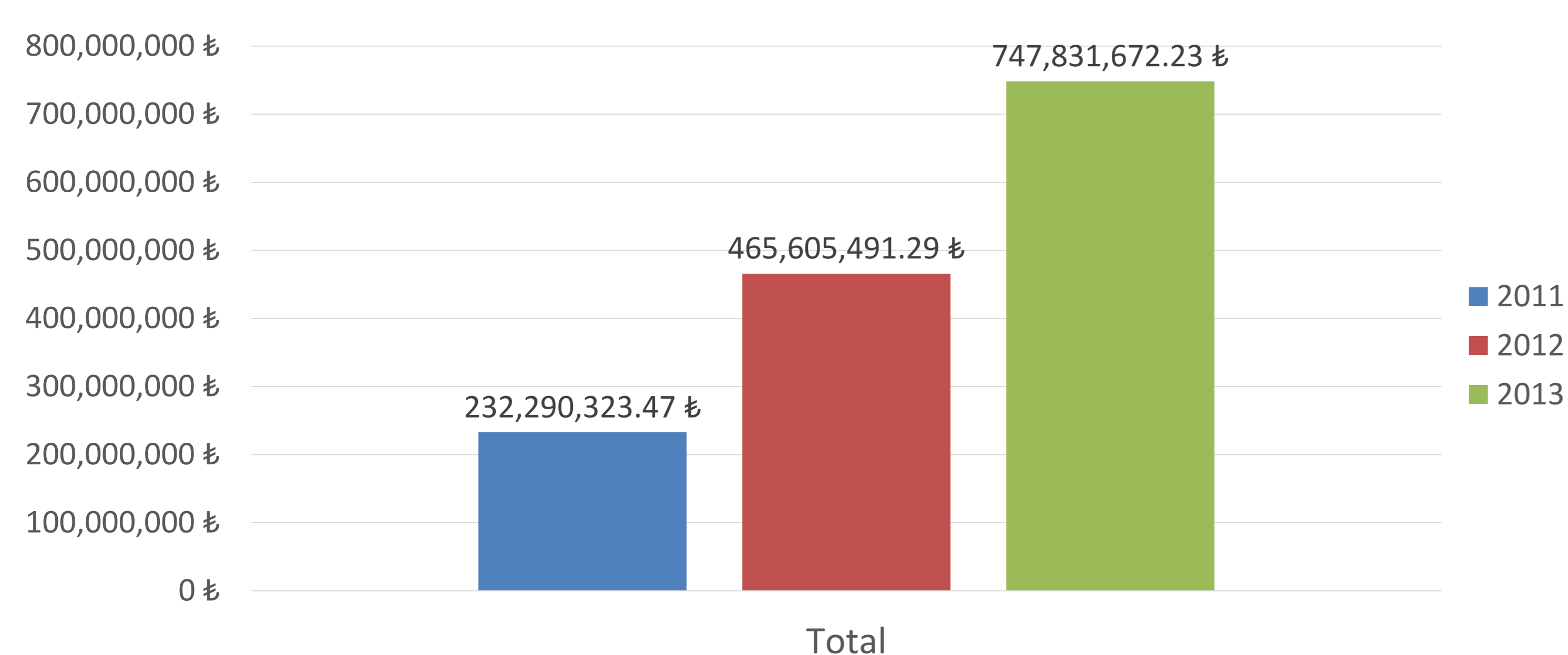
METHODS

This study was designed as an observational, retrospective study. Consumption data of the top 100 imported unlicensed medicines with the highest sales share in total expenses of imported off-label use was taken from the TMMDA database. Descriptive analysis was conducted. Active ingredients of medicines were sorted based on ATC classification. Total units sold of top 100 and average cost per unit of top 100 were also calculated.

RESULTS

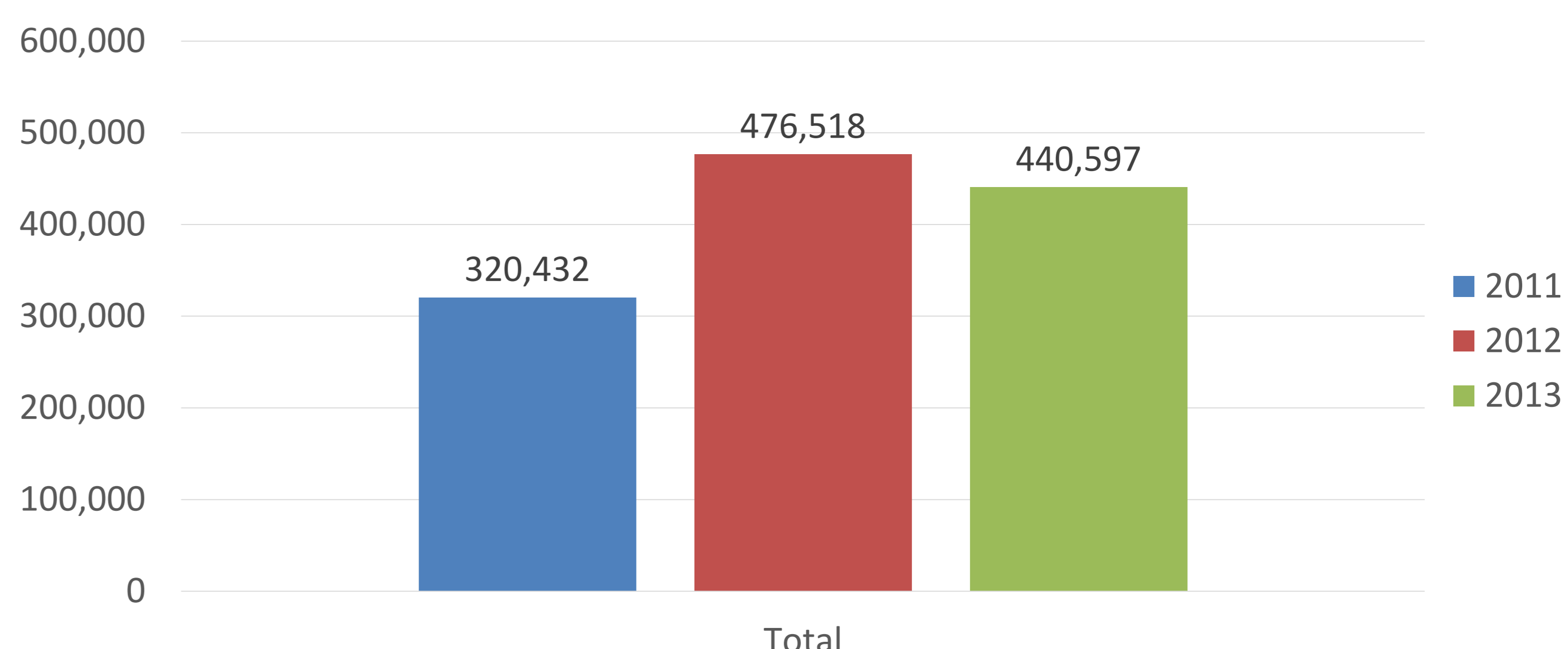
The analysis showed that cost of the top 100 imported unlicensed medicines increased every year from TL 232 billion to TL 747 billion between 2011 and 2013, respectively.

Figure 1: Top 100 medicines for 2011 to 2013 by total sale



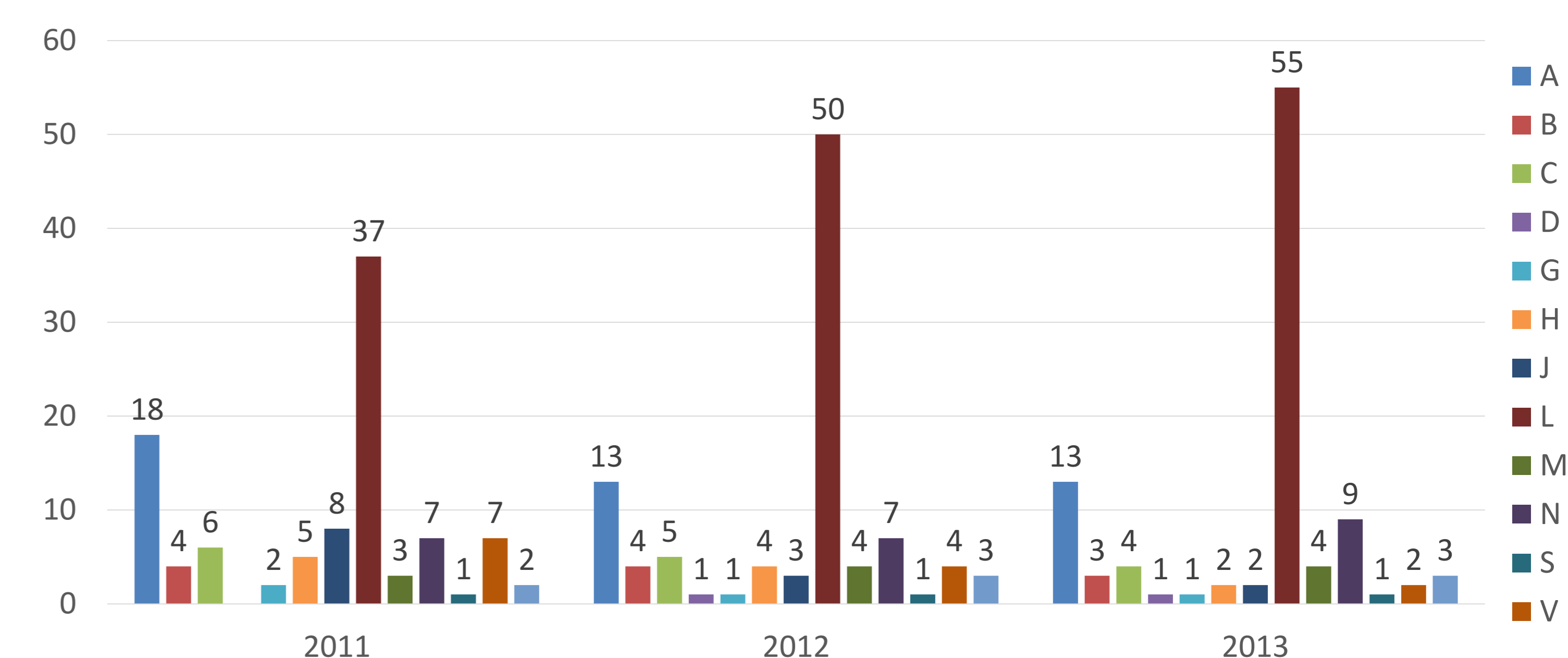
While total units sold of top 100 were 320,342 in 2011, it reached to 476,518 in 2012 and then decreased to 440,597 in 2013.

Figure 2: Top 100 medicines for 2011 to 2013 by units sold



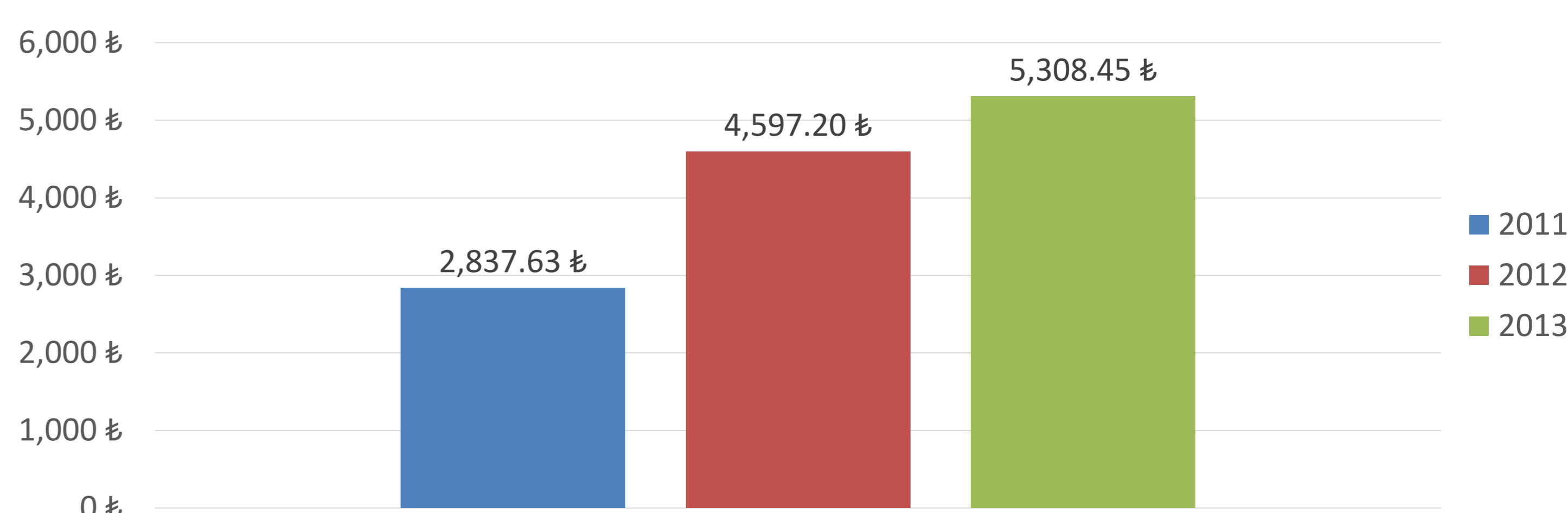
According to the ATC code, L group (Antineoplastic and immunomodulating agents) had the highest number of active ingredients in top 100. In addition to this, the number of L group medicines rose from 37 to 55 between 2011 and 2013.

Figure 3: Number of active ingredients of top 100 medicines between 2011 and 2013 by ATC classification



The average cost per unit increased from TL 2,837 to TL 5,308 in the same period.

Figure 4: The average cost per unit of top 100 medicines between 2011 and 2013



CONCLUSIONS

While the total cost of top 100 unlicensed medicines increased between 2011 and 2013, total units sold decreased in 2013. It can be understood from Figure 4 that the average cost per unit of top 100 medicines increased between 2011 and 2013. It may be considered that the rise of average cost per unit of top 100 comes from L group (whose number changed from 37 to 55 between 2011 and 2013 in top 100 medicines). Therefore some cost-containment measures (especially for antineoplastic medicines) should be taken to reduce this cost without risking the patients' access to innovative medicines.

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