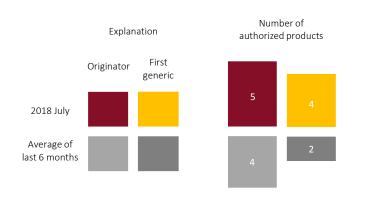
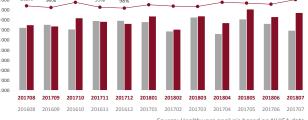


Changes to subsidized medicinal product categories, July 2018





Source: Healthware analysis based on NHIFA data

Number of

reimbursed products

Source: Healthware analysis based on NHIFA data

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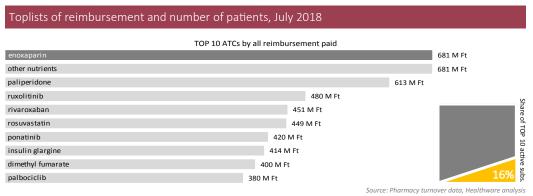
Applications for

reimbursement



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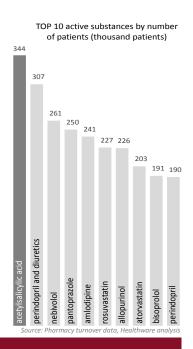
Market data



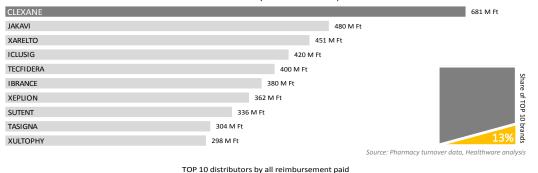


Average number of medical sales reps

Source: NHIFA data, Healthware analysis



TOP 10 brands by all reimbursement paid





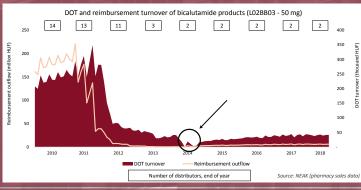
Threats of preferred reference price zone system - Case study

The main goal of introducing the preferred reference price zone in 2011 was to enhance the slowing savings of the preceding reference pricing system, by introducing a degressive reimbursement zone. Seven years of the application provided several examples, drawing our attention to the potential threats of the system. The low price of active substances, which are at the last phase of their lifecycle and have many generic market players, leads to the reduction of the number of distributors. In extreme cases, this can threat the market supply, and/or might lead to processes, counter to the intentions of the system, namely to price increase.

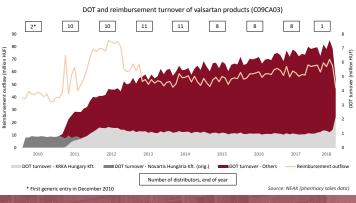
In our current case study, we review two cases, where price increase could happen in order to secure the sustainability of supply, the cases of bicalutamide (L02BB03 – 50 mg) and valsartan (C09CA03)¹.

In the case of the bicalutamide 50 mg tablet, effects of the 2011 changes in regulation are well observable. The first chart shows the DOT turnover, reimbursement outflow and the number of distributors. After 2011 the price started declining gradually, at the same time turnover and the number of distributors also decreased (2012: 11 distributors, 2013: 3 distributors on the market). Our data shows only the tendencies in the reimbursed category. In 2014 there was a point where bicalutamide substance had no turnover and started to regain it only after a price increase, with the participation of two distributors.

to regain it only after a price increase, with the participation of two distributors. The price correction needed in these situations cause a significant additional expenditure for the Health Fund. In the following case of valsartan, we calculate the extent of this extra cost caused by a forced price increase.



In the lifecycle of valsartan (C09CA03) we can also observe a dynamic price reduction process, starting after the generic entry, which is shown in the second chart in the relation between DOT turnover and reimbursement outflow. Between 2014 and 2018 the number of distributors decreased from 11 to 7, and in the summer of 2018 due to an external event – contamination during the manufacturing process – valsartan-containing products of many distributors were recalled all across Europe².



Only products of KRKA Hungary Kft. are available on the Hungarian market now. The results of this is already visible in the data of drug list September 2018³. The valsartan-containing products were withdrawn from the FX process, the price of the remaining two medicines (Valsacor 80mg and 160 mg) were increased by 30.07 and 30.08 %, which was probably reasoned with the increased demand and the secure market supply. According to our estimation, this price increase results a significant burden on the drug budget in the next period.

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Threats of preferred reference price zone system - Case study

In our following estimation (see in the table) we made calculation for two scenarios, regarding the Health Fund's expenditures (valsartan products), and compared them in the period of September-December 2018. In both cases we assumed no change in the demand of these products (monthly DOT turnover = average of monthly DOT turnover in April – June), and assumed that the distributors on the market can ensure the coverage of the whole market.

In the first version, with unchanged market structure — compared to June 2018 — we calculated with 9.25 HUF daily reimbursement outflow, in the second version — where we modelled the current situation - we used the increased price and 55% nominal reimbursement of the two KRKA products on the market. The daily reimbursement outflow in this scenario is 13.65 HUF (it means approximately 390 million HUF total reimbursement outflow for the period of September-December 2018), which leads to a total additional cost of approximately 126 million HUF for the Health Fund until the end of the year, and 354.5 million HUF in the next 12 months.

Calculation of Health Fund's extra cost	Average	Same market structure	New market structure	Difference	Average	Same market structure	New market structure	Difference
	Apr. 2018 June 2018.		Sept. 2018 - Dec. 2018		Last 12 months		Sept. 2018 - Aug. 2018	
Reimbursement outflow	66 188 573	264 754 291	390 796 126	126 041 835	63 106 097	757 273 169	1 111 854 317	354 581 148
DOT turnover	7 155 195	28 620 781	28 620 781	-	6 785 750	81 429 004	81 429 004	-
Reimbursemet outflow per day	9,25	9,25	13,65	4,40	9,30	9,30	13,65	4,35
Source: HW calculation based on NEAK data								

There is no doubt that the present reference pricing system can have a remarkable outcome, but the presented cases highlight some threats – already stated many times by us – which could be significantly reduced by refining the system.

A few – otherwise inter-related – phenomenon, which occurs theoretically (and based on the above mentioned examples, also in reality) following a significant erosion of prices can be named as risks and threats of the current preferred reference pricing system. These are the following:

- number of distributors of reimbursed products might decrease extremely;
 significant part of demand can switch to the non-reimbursed market, out
- of the control and scope of the payer;
- difficulties in supply might occur in case of qualitative probler
- \blacklozenge security of supply, restored through price increase.

The risks set out above typically strengthen in the last phase of the product's life-cycle, so we need changes which provide solution especially in this stage. According to our proposal, a new financing method should be used in the cases of substances after the 6-8-10th reference pricing cycle (which means that these substances are over the most part of the price erosion): a public procurement with only one winner, which would give the whole market to the winner for one year, in return for supply security guarantees. In the public procurement process it would be not possible to submit a price higher than the one determined in the last reference pricing process, the winner product would be distributed under the name of NEAK, to exclude promotion activities.

Moreover, we suggest the regulation of these substances' non-reimbursed market for the interest of the patients' protection, for example by determining maximized prices.

