• <b>HEALTH</b> WARE	

# Actualities of Hungarian pharmaceutical financing market



Million HUFs 45 000

201905

201907 201908 201909 201910 201911 201912

201906







in

H-1093 Budapest Közraktár st. 30-<u>32. 7th floor. I + 36-1-324-2050</u>

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1119

105%

201805 201806 201807 201808 201809 201810 201811 201812 201901 201902 201903 201904

202001 202002

Source: Healthware analysis based on NHIFA data



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### Market data

Toplists of reimbursement and number of patients, April 2020 TOP 10 ATCs by all reimbursement paid ruxolitinib 786 M Ft other nutrients 651 M Ft palbociclib 636 M Ft enoxaparin 628 M Ft Share of TOP 10 active paliperidone 607 M Ft dimethyl fumarate 524 M F1 apixaban 515 M Ft rivaroxaban 484 M Ft rosuvastatin 442 M Ft subs formoterol and beclometasone 368 M Ft ource: Pharmacy turnover data, Healthware analysis





Average number of medical sales reps

Source: NHIFA data, Healthware analysis TOP 10 active substances by number of patients (thousand patients)



TOP 10 brands by all reimbursement paid



Novartis				3 553 M Ft
Pfizer			2 104 M Ft	
SANOFI		1 88	5 M Ft	
EGIS		1 747 M F		<u>र</u>
Novo Nordisk		1 653 M Ft		Share of TOP
Richter Gedeon		1 643 M Ft		offc
TEVA	1 273 M Ft			
Boehringer Ingelheim	1 208 M Ft			10 distributors 54%
JANSSEN-CILAG	1 079 M Ft			ribu
AstraZeneca	985 M Ft			<b>54%</b> g
				Source: Pharmacy turnover data, Healthware analysis

### Innovative price reductions - Case study

This year we became aware of a new phenomenon in the circle of reimbursed pharmaceuticals – in several cases, innovative, patent-protected products had reduced their prices, which has not been typical in the frames of the Hungarian reimbursement system. In our current case study, we analyze the reasons/background for these price reductions and try to discover the consequences of these tendencies.

Between January and July 2020, 150 public price reduction has happened in the Hungarian reimbursed pharma market – concerning 86 brands and 132 SKUs. The majority of them – according to the previous practice - were due to the quarterly FX process (reference pricing system) - including the reductions of June (early first-round bids of the July FX).

The focus of our case study is the 18 –mainly originator - brands (31 cases), whose price reduction was not linked to the FX process. In the first six months of the year (January – July 2020), the number of these price cuts was unusually high considering the history of the Hungarian pharma market

20 and 15

vith price

Between 2016 and 2019, only three brands have had not FX-related price reduction (Figure 2). In the first half of 2020, the number of these cases was six-times higher, 18 brands initialized price cuts this year. The question is whether these are sporadic cases, or is this the beginning of a new practice, becoming regular in the future? And who benefits from it?

First, in our analyses, we try to discover the possible reasons behind the not expected, and not F related price reductions. We classified the 18 brands on the following three aspects (Figure 3):

(a) whether the brand had a new submission – a new indication, preparation
(b) whether there is or expected to be any generic/biosimilar on the market
(c) whether there is an expired price-volume agreement (PVA) for the product

Figure 1: SKUs with price reduction between 80 202001-202007 59 Number of SKUs 53 60 34 40 20 75% 3 1 0 202005 202006 202007 202001 202004 Number of brands 22 42 2 34 FX related Other urce: NHIA

Figure 2: Price reductions not related to FX process

2016-2020

2018

2019

Not PVA related

2020

2017

PVA related

2016

In the cases of a) and c), changes are taking place due to amendments in NEAK procedures. Unlike before, NEAK revises international prices not only at the submission of the dossiers (in line with the regulation) but also before the Health Technology Assessment discussion, at the time of the publication and when renegotiating the terms of the existing PVAs.

Among the examined cases, the price change of 4 brands was related to reimbursement inclusion, (a). The price reduction of 4 other brands (7 SKUs) has linked to the presence of generic products or a threat posed by them (b). In some of these cases, the price – and the copay - have already been pushed down by the generic/biosimilar products, forcing the price cut of the originator. However, price reduction can be also a preventive strategy to undermine generic appearance on the market.



We found 12 brands having price-volume agreements (c). Their PVAs – except for one – were valid until the end of 2019 – according to the latest published data –, in 10 cases, there seems to be no other rational reason behind the price cuts. For each group, we see products at very different stages of their life cycle, which can have an impact on the extent of their public price cuts.

Considering the average price reduction of products in each category (a, b and c), we found that there has been a larger reduction in those where generics/biosimilars have already appeared or are expected to appear - but are not yet included in the FX process. For these products, an average price reduction of 35% can be observed. The average decrease of the products with PVAs was 25%, while reimbursement inclusion-related average was the lowest, 8%. The prices of the GLIVEC and SANDOSTATIN / SANDOSTATIN LAR brands decreased the most, the former by 60-70% and the latter by 40%.

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## Actualities of Hungarian pharmaceutical financing market

### Innovative price reductions - Case study

These changes are in line with the facts, that a product in the early stage of its life-cycle 1) has European price at a common price level, and 2) probably can realize marginal price cuts due to strict corporate pricing policy rules. This also applies when the distributor initialize the price cuts due to a new indication, SKU, but the Payer can enforce the European lowest price – because of the condiprobably a defensive pricing strategy trying to prevent the generic entrance, since the fixed generic pricing sequence creates a difficult situation for the first generic/biosimilar also with an expected price level discount of 30-40%. The price reduction level of products with PVAs is outstanding, especially if we consider that this process has no clarified legal background.

price reductions, there is no percep-tible change in patient cost burdens, as most of the brands concerned have indication-based reimbursement of 100% (11). The price cuts of (1 brand) reimbursement were both in number and extent more modest. in our analysis, had a negligible change in its list price)<sup>1</sup>.



Figure 5: Brands by the extent of price reduction

and their date of inclusion

2013.12

The size of the bubble presents the monthly consumer price volume of the brand in May 2020

Date of inclusion

.ON Támogatási kategória: ● itemized ac. ● EÜ100 ● EÜ70

2019.12

Source: NHIF

Hence, savings of price reductions are mainly reflected in the Health Fund ("NHIF"). Based on the box turnover data of May 2020, the examined price reductions generate approximately HUF 4 billion fewer reimbursement outflows on an annual basis. However, the calculation may be misleaddiffer from the gross (and public) results. The net reimbursement amounts are likely to remain crease, since Hungary is a reference country in many country.

70%

50%

40%

30%

Extent 20% 10%

It is interesting to look at the date of inclusion of the examined brands - at al price cuts occurred. Figure 5 shows that the most excessive price reducproducts examined, in terms of price

In the early stages of the original brands' life cycle, manufacturers are already willing to start price erosion, even years before the competitive environment created by generics. We see an empty period between 2017 and 2019. The products getting reimbursed during this period have not sub-PVA in this period (2017-2019) may appear in the following years with renegotiation-related (c)

However, an interesting process emerges. In the early stages of the original brands' life cycle, manufacturers are already willing to start price erosion, even years before the competitive environment created by generics. We see an empty period between 2017 and 2019. The products getting reimbursed during this period have not submitted a price reduction request in this year. This may be related to the current practice, that mostly 3-year-long PVAs have been 2019) may appear in the following years with renegotiation-related (c) price reduction.

Legislations only applies to the generic inclusion sequence and the revision of international prices in the reimbursement inclusion procedure, according to the situation at the time of the submission of the dossier. The price reduction at the time of inclusion and PVA-related price modifications are not regulated. Nevertheless, from this year onwards, we see a large number of 'voluntary' price erosion initialized by originator distributors.

Price reductions at the beginning of the life cycle may be a less sensitive issue for the distributor if the net price is significantly below the public price level, however, the volatility of the domestic currency may also make it risky in the long run. As does the - according to the current trends – yearly renegotiation of PVAs (and the price adjustment claim by NHIF related to it), that may cause more dynamic price erosion among originators. As a further uncertainty, it is also unclear what exchange rate is applied in the currency conversion in these cases.

whether there is enough capacity to maintain stantial result can be realized by either of the



- in the case of expected generic or biosimilar appearance, the distributors if they can do so - are willing to cut their public prices to secure their current
- market position • the effect of international reference pricing applied during the PVA negotiaeven though the legal specifics and detailed rules are not well defined right now, and the specific benefits available to actors are also not clear

Although the real benefit from the PVA and international reference pricing-related price reductions is a question, it is worth building up the legal background for it, if this increasingly common process seems to become a permanent part of the Hungarian practice. Due to the extreme volatility of the forint, it is questionable whether this is indeed the best another element in the long-run. Moreover, Hungarian public prices are reference prices high volatility of the forint.



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