

Impact of loss of exclusivity on the expenditure of medicines: an analysis on molecules for which a generic or biosimilar was introduced in the Netherlands after 2012



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Highlights

- Overall objective was to get a better understanding of price erosion of medicines after loss of exclusivity in the Netherlands. The current analysis is restricted to products that have gone off-patent since 2012.
- Intramural molecules witnessed a higher price erosion compared to extramural molecules, resulting in higher savings. Intramural savings are lower than the price erosion which is due to an increase in the usage (number of DDDs).
- Findings from this study suggest that payers in the Netherlands have become increasingly successful in negotiating price reductions after loss of exclusivity.

Objective

To quantify the expenditure of products that have gone off-patent since 2012 and to estimate the savings after loss of exclusivity.

Methods

Molecules that have gone off-patent since 2012 and for which a generic or biosimilar was introduced in the Netherlands were identified. For outpatient drugs, data on the usage and reimbursement were obtained from the publicly available GIP Open Data. For inpatient drugs, reimbursement data were also obtained from the GIP Open Data, whereas the usage was informed from Farminform database (access granted via VIG). The average reimbursement per daily defined dose (DDD) was calculated per calendar year and used to inform a model to quantify the expenditure after loss of exclusivity. Results were presented in the form of relative difference in expenditure per DDD and savings due to patent expiration.

Results

A total of 199 molecules across all 14 ATC levels faced generic launches in the Netherlands between 2012 and 2022. Most molecules included in this analysis are non-biological, outpatient drugs.

Five years after loss of exclusivity, an expenditure erosion of 40% (95% CI: 33% to 46%) was found for all molecules that have gone off-patent since 2012. Inpatient molecules witnessed a higher erosion (57% [53% to 86%]) compared to outpatient molecules (38% [31% to 45%]) (Table 1 and Figure 1).

Table 1: Overview of the calculated average price per DDD, stratified per follow-up period and setting (outpatient [extramural] and inpatient [intramural]).

		No. of Molecules	Price evolution – average price per DDD							
			Year -2	Year -1	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
1-year follow-up	Total	19	244.71	249.39	224.36	140.40	-	-	-	-
	Outpatient	16	268.83	276.54	249.00	161.50	-	-	-	-
	Inpatient	3	116.08	104.62	92.98	27.88	-	-	-	-
2-year follow-up	Total	11	5.552.39	5.819.98	5.739.01	2.387.78	743.28	-	-	-
	Outpatient	8	675.66	918.44	740.03	605.41	353.91	-	-	-
	Inpatient	3	18,557.01	18,890.75	19,069.65	7,140.79	1,781.61	-	-	-
3-year follow-up	Total	24	76.32	75.6	79.48	76.72	69.32	29.13	-	-
	Outpatient	19	15.99	16.22	15.83	15.05	12.58	11.77	-	-
	Inpatient	5	305.56	298.62	321.36	311.06	284.94	95.08	-	-
4-year follow-up	Total	17	14.35	15.17	14.87	15.47	14.17	14.09	14.17	-
	Outpatient	17	14.35	15.17	14.87	15.47	14.17	14.09	14.17	-
	Inpatient	-	-	-	-	-	-	-	-	-
5-year follow-up	Total	86	10.59	9.62	9.25	7.82	5.68	4.70	4.15	4.00
	Outpatient	85	10.08	9.10	8.76	7.33	5.23	4.30	3.84	3.74
	Inpatient	1	53.87	53.33	51.05	49.14	44.01	38.93	29.93	26.19

Molecules with a higher expenditure before patent expiration generally witnessed a higher price erosion. When corrected for relative usage, the weighted expenditure erosion increased to 63%, which was again found to be higher for inpatient molecules (88%) than for outpatient molecules (62%). Reduction in expenditure did not immediately translate into savings, as some molecules experienced an increase in use after loss of exclusivity (Figure 1).

Recently expired molecules showed a similar trend in unweighted price erosion as molecules with a longer follow-up but a more aggressive decline in weighted price erosion (Figure 2). This difference between unweighted and weighted price erosion can mainly be caused by intramural molecules.

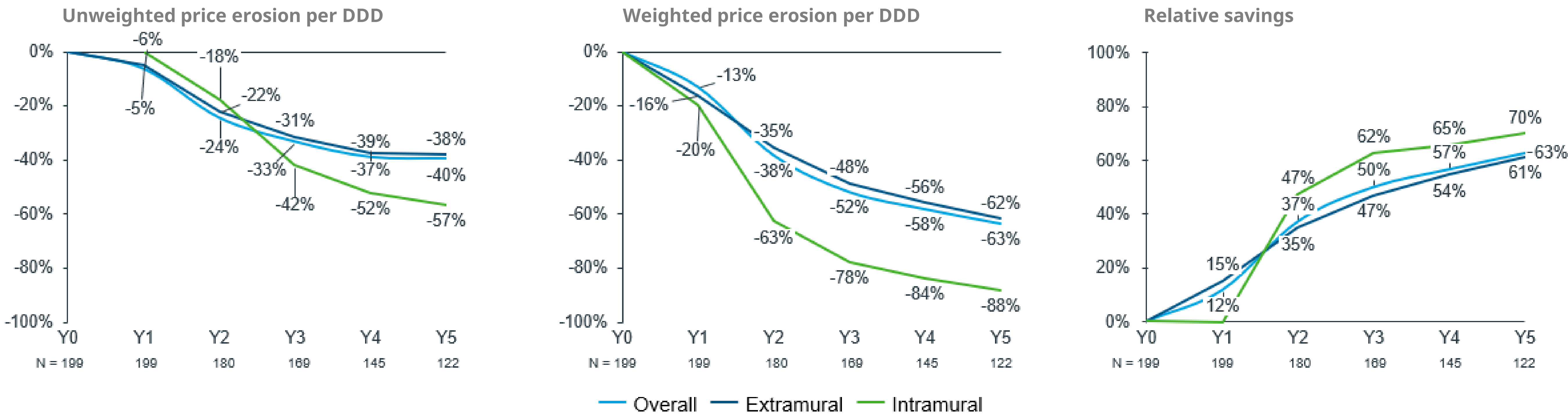


Figure 1: **left** unweighted price erosion per DDD post loss of exclusivity, calculated as the year-on-year (YoY) difference (%), stratified per setting (outpatient [extramural] or inpatient [intramural]). **Middle** weighted price erosion per DDD post loss of exclusivity, calculated as the YoY difference (%), stratified per setting. **Right** relative savings post loss of exclusivity, calculated as the YoY difference (%), stratified per setting.

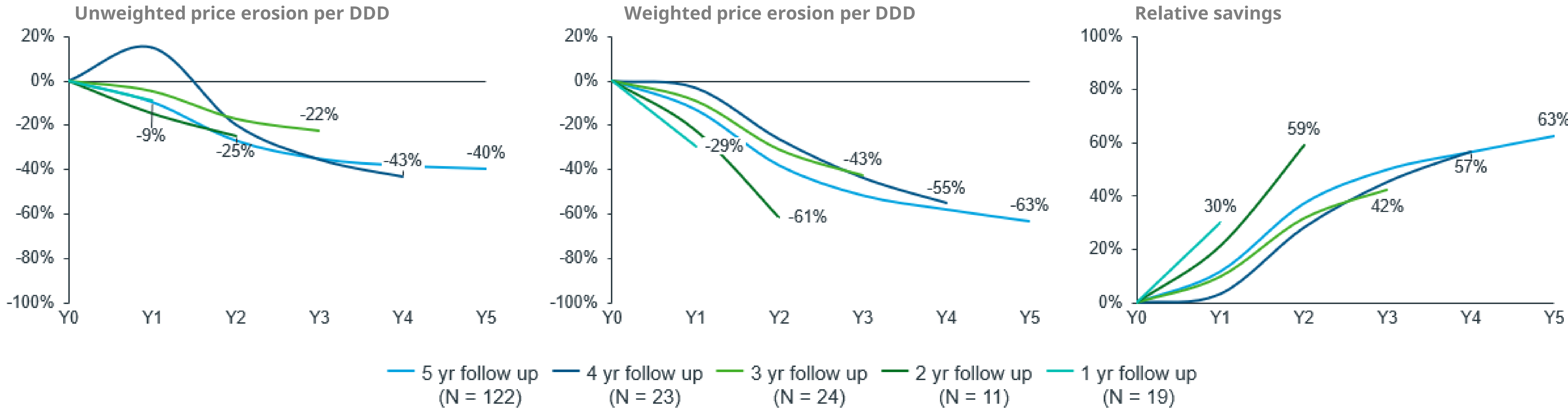


Figure 2: **left** unweighted price erosion per DDD post loss of exclusivity, calculated as the year-on-year (YoY) difference (%), stratified per follow-up period. **Middle** weighted price erosion per DDD post loss of exclusivity, calculated as the YoY difference (%), stratified per follow-up period. **Right** relative savings post loss of exclusivity, calculated as the YoY difference (%), stratified per follow-up period.

Discussion

Although a rapid decline in the average price per DD was observed within a year after loss of exclusivity, the timing of price erosion differed across molecules. The current analysis is based on calculations per annum and did not take into consideration the exact timing of patent expiration. The results from the current analysis are in line with a previous research by Van der Schans *et al.* (2020) that demonstrated a higher price erosion for products with a higher annual revenue.

Conclusions

Trends were found in expenditure after loss of exclusivity, with the highest price erosion observed in the first three years after patent expiration, after which a plateau formed. This study also highlights that the rate of erosion has increased over time which may suggest that payers have become increasingly successful in negotiating price reductions after loss of exclusivity.

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