



# Loss of Exclusivity analysis

Evaluation of the financial and market impact on a pharmaceutical company when a drug's patent protection expires, and generic competition enters the market

# High market attractiveness and likely entry of >5 competitors will lead to a share decrease of 70-90% for [Originator drug] (1/5)

SAMPLE

## LOSS OF EXCLUSIVITY

/ PRELIMINARY

Categories	Underlying characteristics		Rationale	Impact on originator market penetration
① Market attractiveness	Revenue	~\$12.5B <sup>1</sup>	Global net sales in 2021 are >\$5B for [Originator drug] franchise, positioning it as a blockbuster with a highly attractive market for generics	➡
	Volume	~7B <sup>2</sup>	Exceptionally high-volume highlights large potential for generics in the diabetes type-II space	➡
② Competition	# of entrants	>5	>5 generic entrants anticipated for [Originator drug] from litigation data and dossier filings	➡
	Biological	No	[Originator drug] is a non-biological, small molecule drug implying that generics do not face any additional challenges when copying the originator	-
	Early entry Generic	No	As of now, there are no signs that there will be an early entry generic impacting the market penetration of the originator in an early stage	-
③ Other factors	Geo	68% US, 5% EU Archetype 1, 5% EU Archetype 2	[Originator drug] is mainly sold in the USA with some additional exposure to countries in Europe (UK & Germany) with high generic substitution, highlighting an exposure to countries that historically show a high penetration of generics	➡
	ACT	A10BH01	[Originator drug] is a drug used in disease information (ATC XX) as it is a [...] inhibitor aiming to lower blood glucose which is sold in pharmacies  For this type of drug, there are no additional regulations/ hurdles in place that would prevent generics to enter the market	➡
④ Share loss				70-90%

Note: 1) Revenue includes ~\$8.5B revenue from [Originator drug] and ~\$4B from [Originator drug], IQVIA data reflecting gross sales, which can differ from company reported sales;

2) Volume includes ~3B units from [Originator drug] and ~4B units from [Originator drug] | Source: IQVIA; Market participant interviews

Impact on originator market penetration: ➡ Positive ➡ Neutral ➡ Negative

# Selection of comparable LoE cases since 2017 gives with 34 individual cases to estimate originator volume decay (2/5)

SAMPLE

LOSS OF EXCLUSIVITY

SHARE LOSS

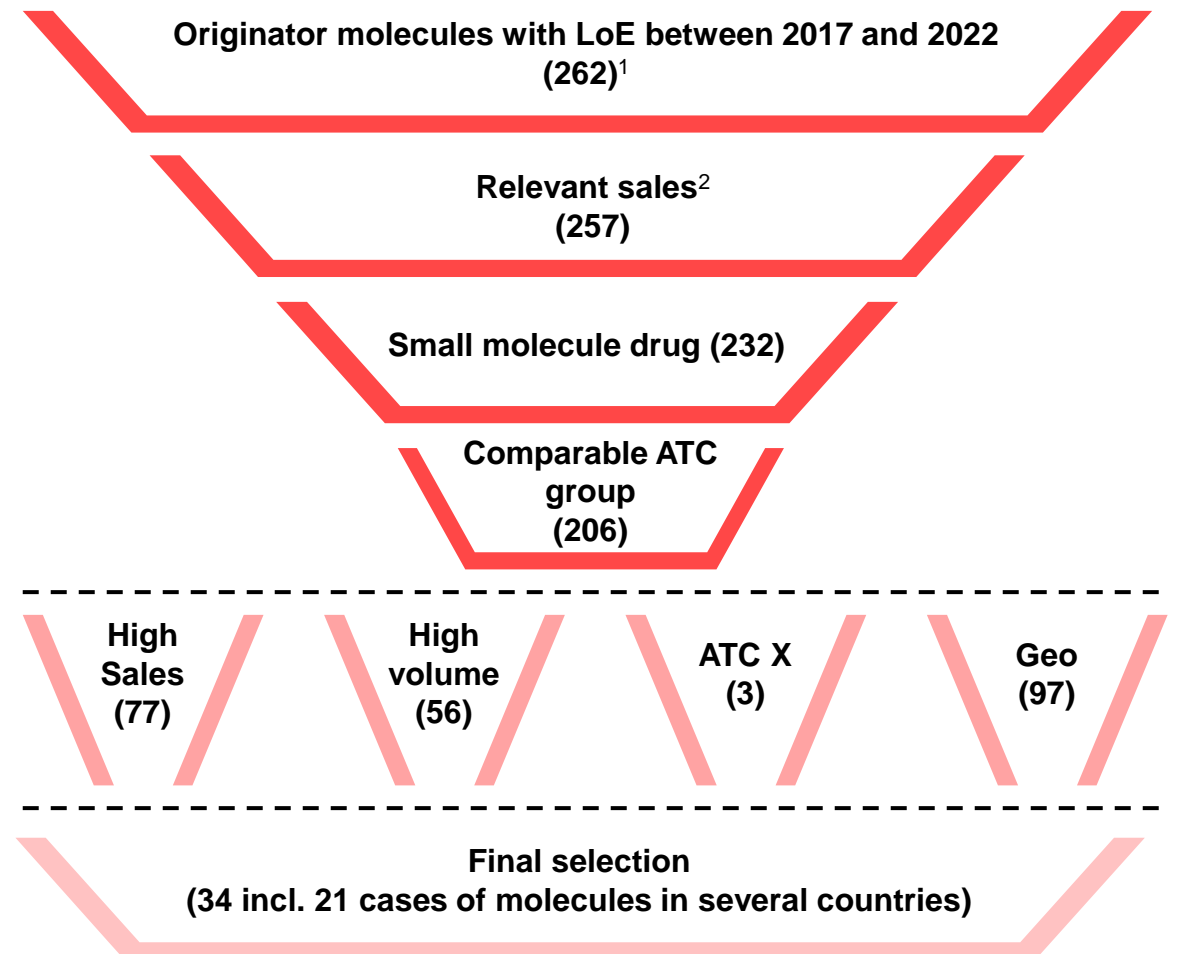
/ METHODOLOGY

## Methodology

- Empirical analysis of how branded drugs **change in price, volume and sales** following loss of exclusivity is based on selection of comparable, historical LoE cases
- **All originator molecules since 2017** that have a **LoE between 2018 and 2022** have been selected from the IQVIA database
- This selection is **narrowed to drugs**, which are comparable to [Originator drug] by excluding **products with neglectable sales, biological products**, and products in **ATC groups** that have **higher entry barriers** due to regulations and research costs (i.e., R: Respiratory System and N: Nervous System)
- We use the remaining 195 originators as our **selection of comparable LoE cases** analyzing changes especially in volume after LoE
- Thereby, we **consider additional factors to refine our analysis** by screening for drugs that meet a least two of the following criteria
  - Originator has high sales (i.e., >\$1 B in US and >\$75 M in European countries) as [Originator drug] displays global net sales of ~\$X.X B
  - The drug has a high sales volume (>50 M units) as [Originator drug] is also a volume-driven
  - There is an overlap in the ATC group (i.e., A)
  - The Originators has exposure to relevant geos (USA, Germany, and UK) as 68% of [Originator drug] sales come from the US and 5% from EU Archetype 1 countries
- The **final selection is manually adjusted** to exclude drugs which pass the filter criteria but are still not comparable to [Originator drug] for case-specific reasons (e.g., exclusion of Viagra drugs and steroids)

Note: 1) Excluding originator molecules without complete sales data; 2) Excluding products with <\$50 M sales in US and <\$5 M sales in Germany and UK  
Source: IQVIA

## Funnel



# Sales drop of ~80% in US, DE, and GB driven by volume decay, while Originators in Spain and Italy are able to maintain volume through price reduction (3/5)

SAMPLE

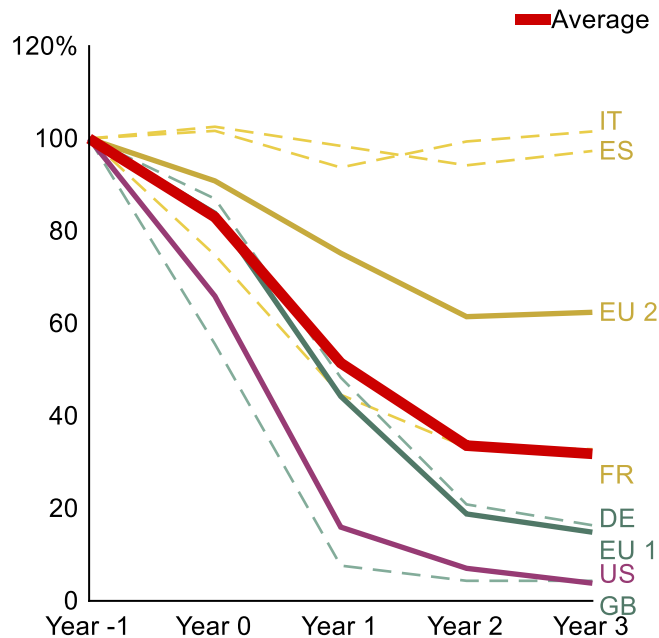
LOSS OF EXCLUSIVITY

SHARE LOSS

/SAMPLE OUTPUT

## Volume

Sold units post-LoE (indexed on LoE year)

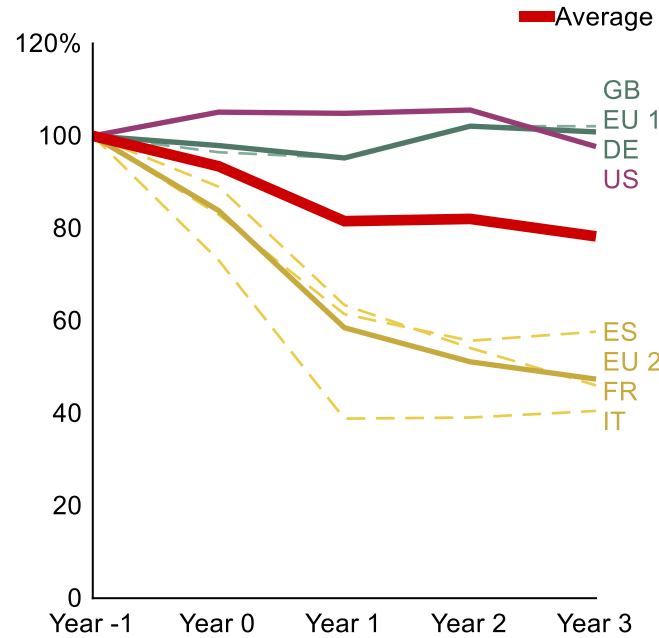


N	28	28	28	22	11
Average	100%	83%	51%	34%	32%
US	100%	66%	16%	7%	4%
EU 1	100%	84%	44%	19%	15%
EU 2	100%	91%	75%	61%	62%

Note: Year 3 includes Year 2 Generics penetration if there are no values available in Year 3  
Source: IQVIA

## Price

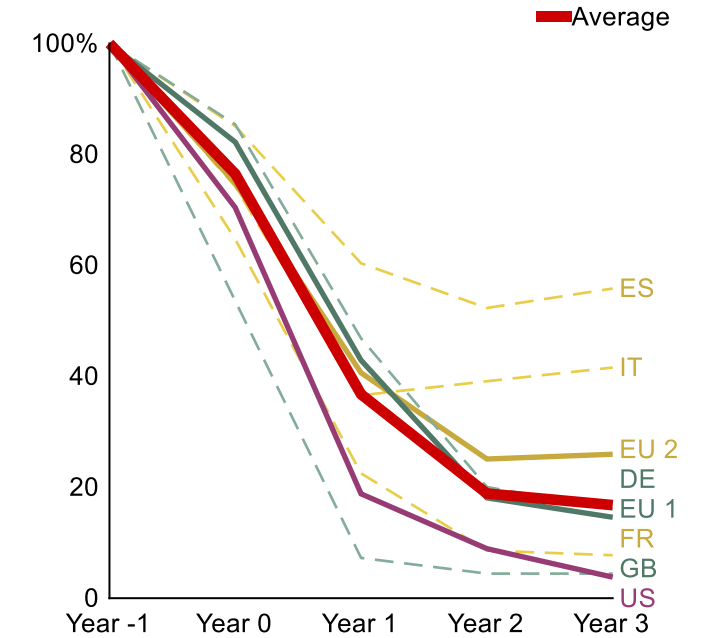
Price (indexed on LoE year)



N	28	28	28	22	11
Average	100%	93%	82%	82%	78%
US	100%	105%	105%	106%	98%
EU 1	100%	98%	95%	102%	101%
EU 2	100%	84%	59%	51%	47%

## Sales

Sales (indexed on LoE year)



N	28	28	28	22	11
Average	100%	76%	37%	19%	17%
US	100%	70%	19%	9%	4%
EU 1	100%	82%	43%	18%	15%
EU 2	100%	75%	41%	25%	26%

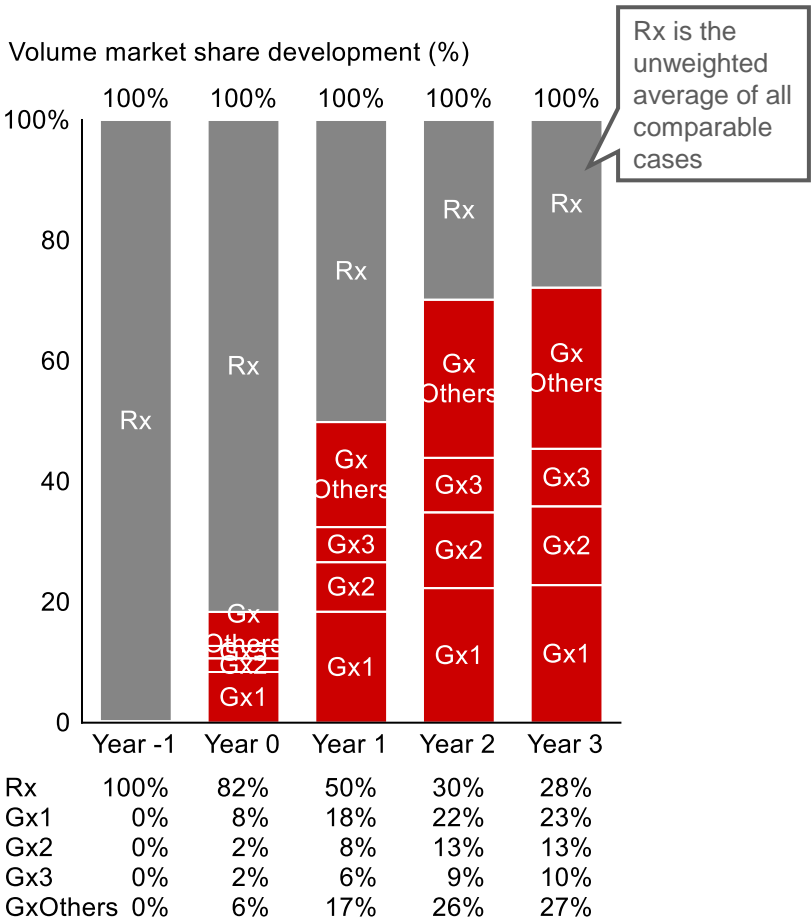


Comparable LoE cases show, on average, Generics are expected to gain up ~70% market share within 3 years, with varying magnitude for timing of entrance (4/5)

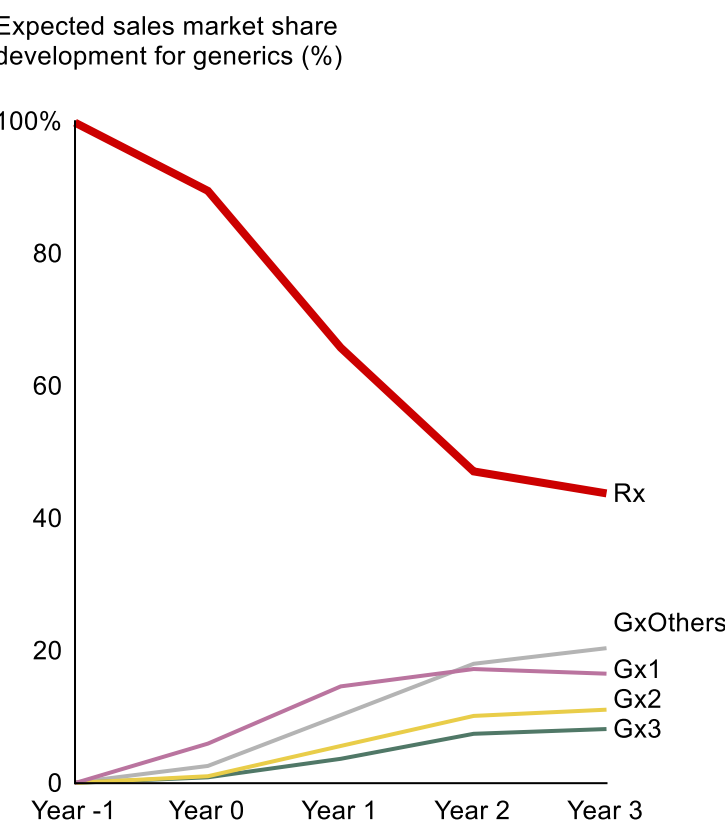
SAMPLE

LOSS OF EXCLUSIVITY      SHARE LOSS      / SAMPLE OUTPUT

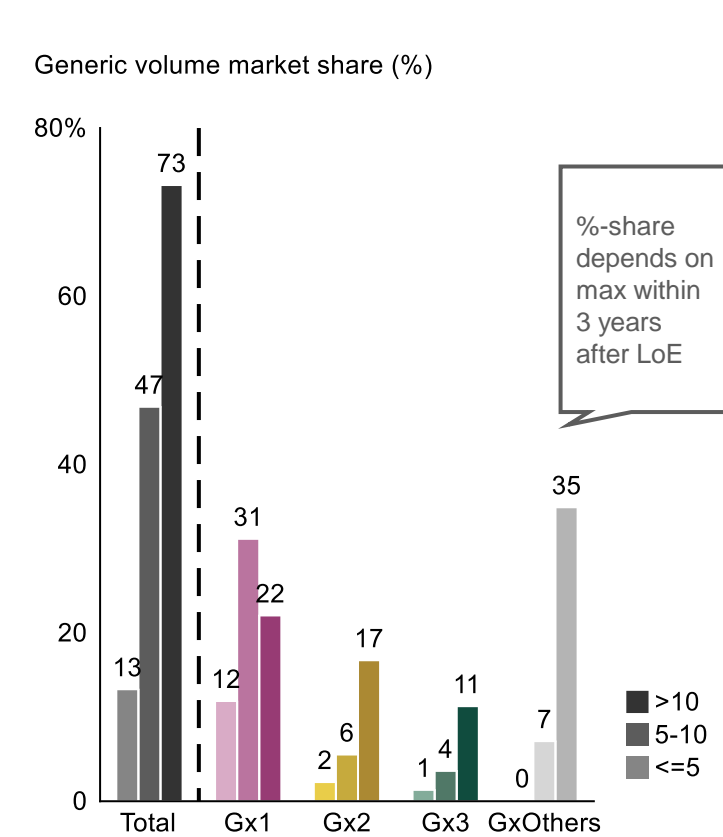
Generics market share increase



Expected sales share for Generics



Gain of Generics by share by # of entrants



Note: Year 3 includes Year 2 Generics penetration if there are no values available in Year 3; EU 1 includes Originators from Germany and the UK, while EU 2 includes Originators from France, Italy, and Spain  
Source: IQVIA

# Comparable LoE cases show, on average, a decline in Originator market share of ~70% with exceptionally strong decline in the US (5/5)

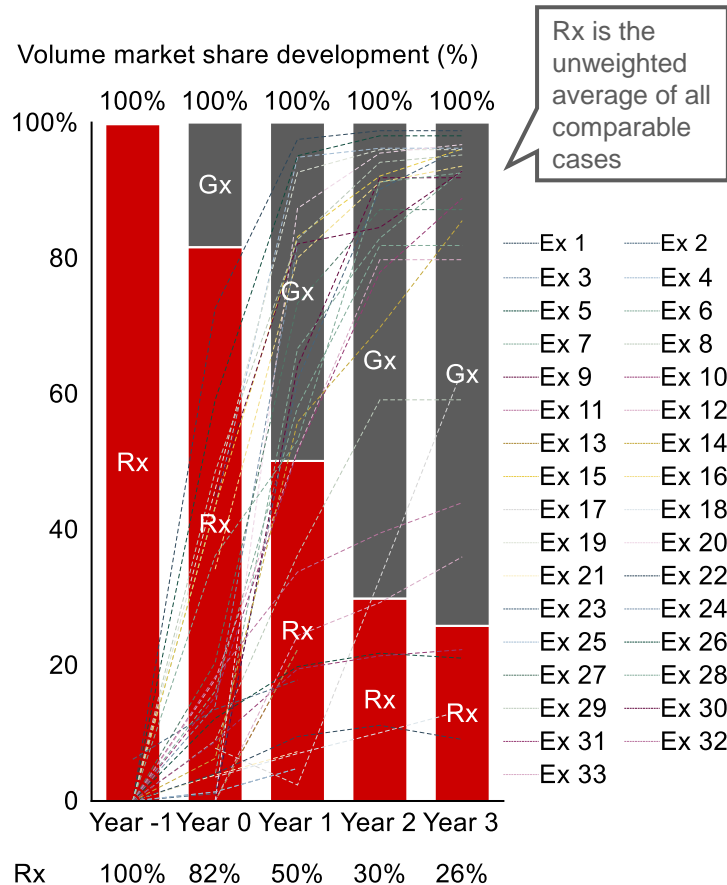
SAMPLE

LOSS OF EXCLUSIVITY

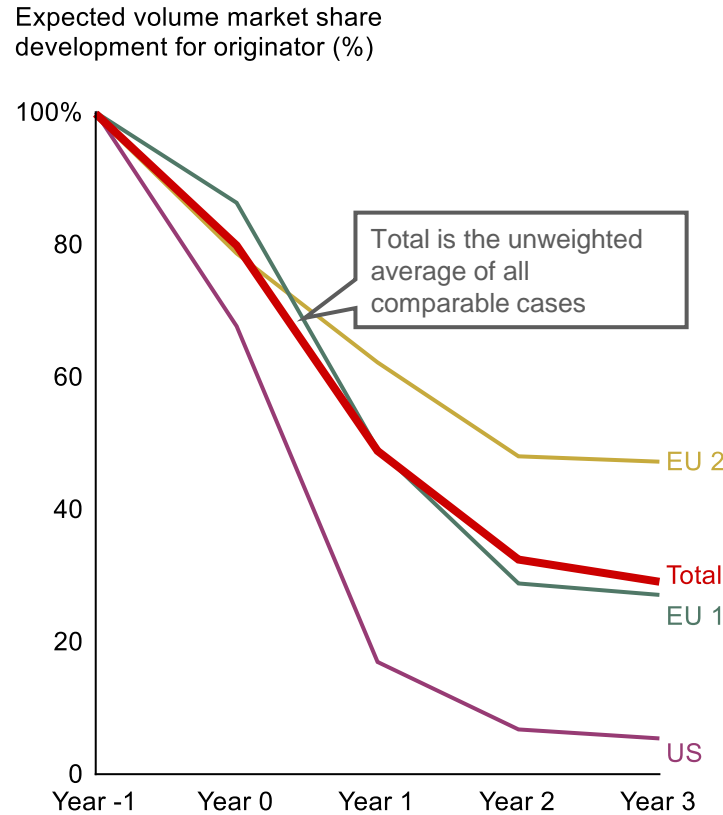
SHARE LOSS

/ SAMPLE OUTPUT

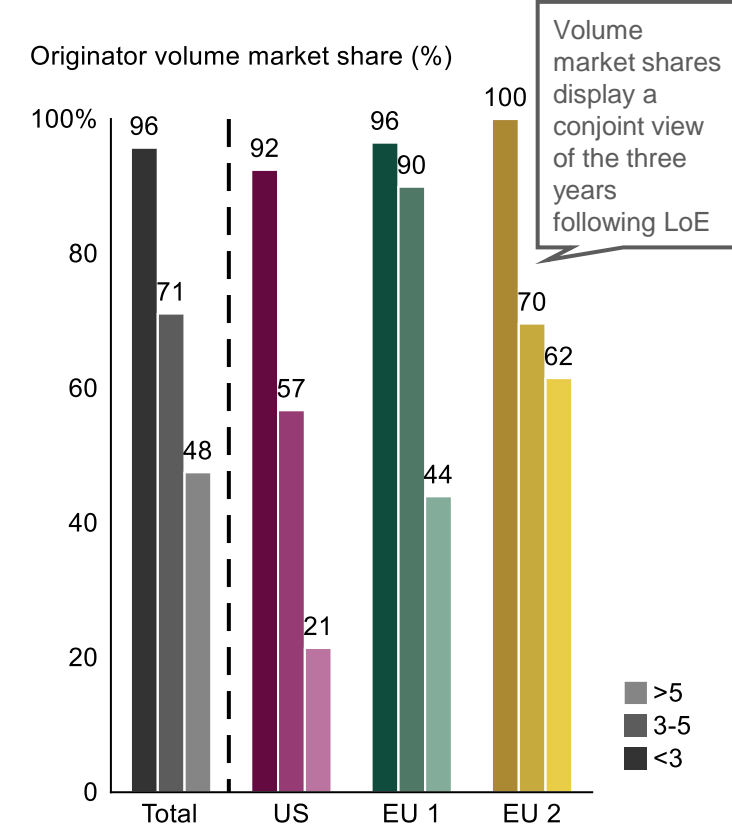
## Originator market share loss over years



## Expected development for Originator



## Loss of Originator share by # of entrants



Note: Year 3 includes Year 2 Generics penetration if there are no values available in Year 3; EU 1 includes Originators from Germany and the UK, while EU 2 includes Originators from France, Italy, and Spain  
Source: IQVIA