

Economics of generics manufacturers

Report

Generics manufacturers' performance on the French retail market

Gemme considered the support of Smart Pharma Consulting to assess generics manufacturers' performance in France and to put into perspective their footprint

Introduction



Context and objectives

- **Generics industry supports local employment in France:**
 - 15,000 direct and indirect jobs
 - 60 production sites
 - 55% of marketed generics made in France
- However, **generics manufacturers have lower operating margins** than other drug manufacturers
- Some **externalities** have a **major deleterious impact:**
 - The **safeguard clause** (known as contribution M), applicable to generic drugs since 2019
 - Regular **price cuts** decided in the context of the LFSS¹
 - **Inflation**, which has an impact on the main cost items
- In this context, **Gemme** considered the **support of Smart Pharma Consulting** to carry out a **study to alert government and politicians** to the **precarious situation of generics manufacturers**



Methodology

- 1 **Collection of market data**
 - Overview of the structure and dynamics of the market for generics delivered in retail pharmacies
- 2 **Analysis of the generics manufacturers' performance**
 - Based on a sample of 7 companies accounting for 88% of the market for generics delivered in retail pharmacies in 2021



- 3 **Generics manufacturers' footprint in France**

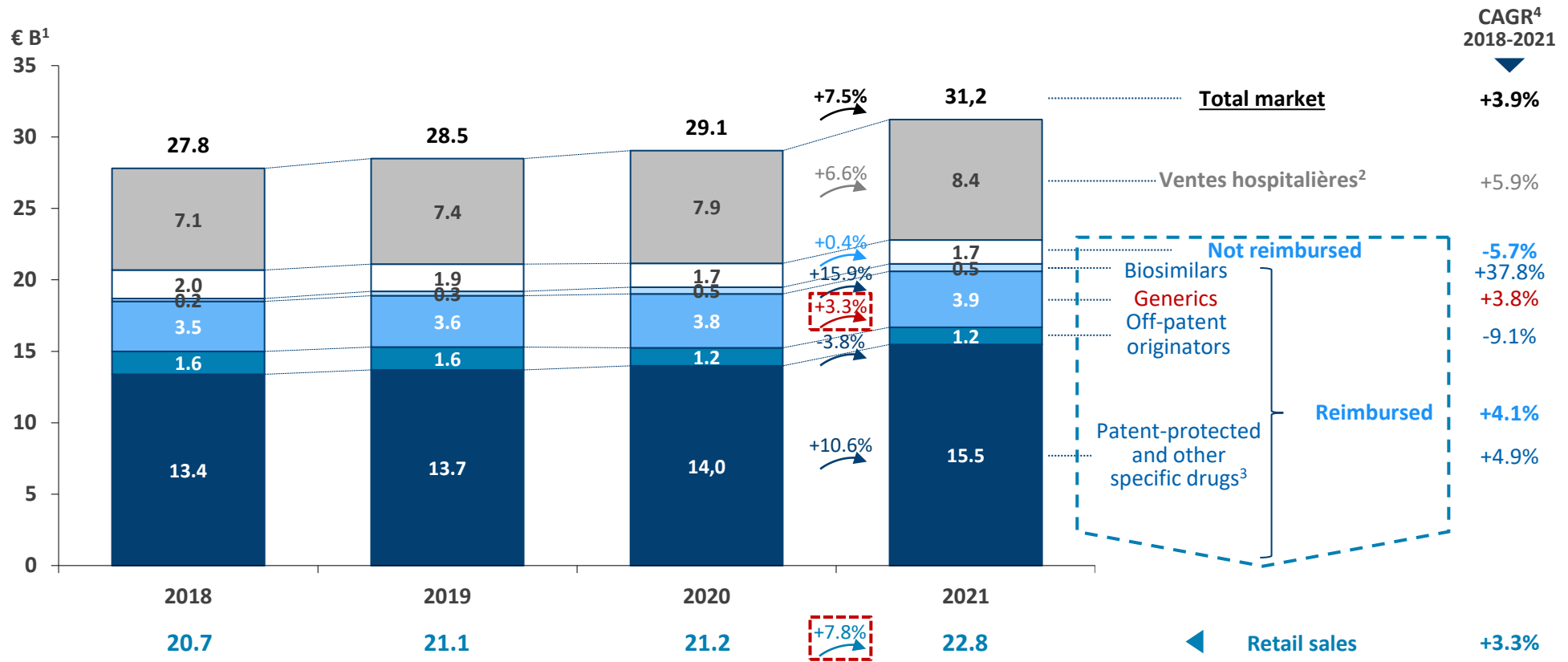
Employment,
production and supply

Savings for Social
Security

Economic balance of
retail pharmacies

In 2021, the retail drugs market increased by 7.8%, while retail generics grew 2.4 times slower, with a growth rate limited to 3.3%

Evolution of drugs sales by segment (2018 – 2021)



Sources : GERS Dashboard – Smart Pharma Consulting estimates

¹ Constant ex-factory prices – ² Estimated net of a 33% average discount rate, including hospital sales of biosimilars, products invoiced on top of “T2A” and reassigned medicines –

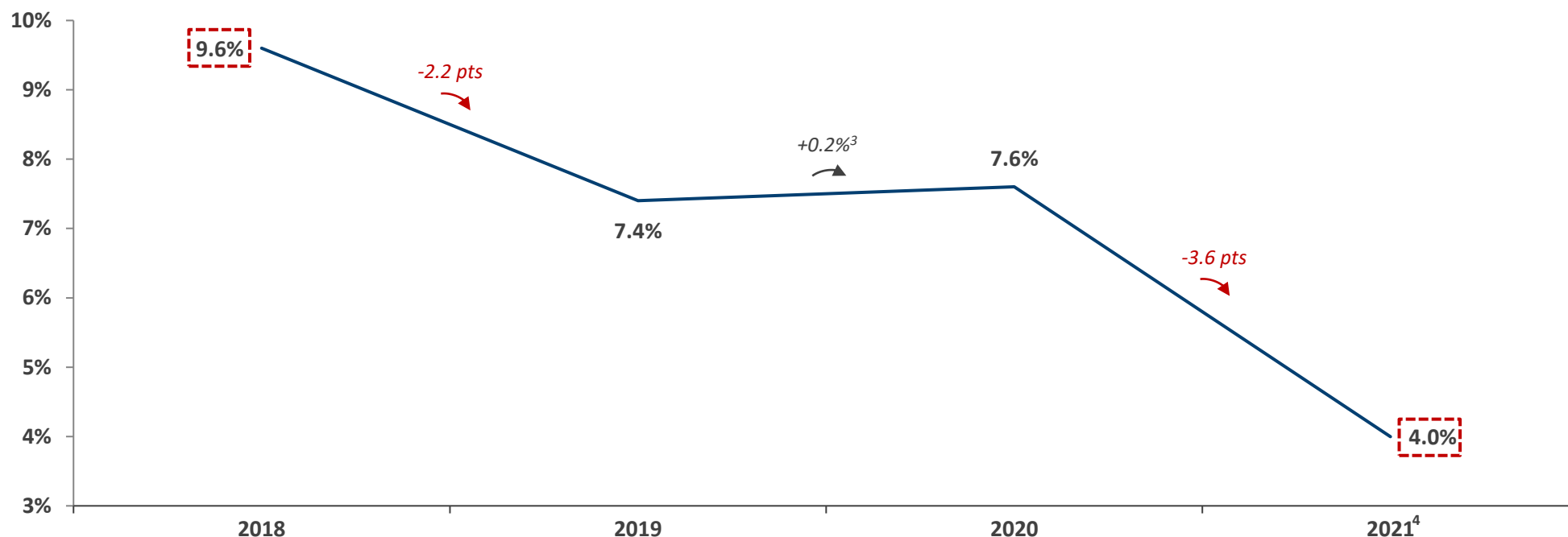
³ Sales of drugs whose patent has not expired and of other specific products (e.g., calcium, sodium, potassium, paracetamol) – ⁴ Compound annual growth rate

Generics manufacturers EBITDA¹ rate decreased from 9.6% in 2018 to 4.0% in 2021, with a particularly marked drop in 2021 (-3.6 points)

Profitability of generics manufacturers operating in France (2018 – 2021)

Profitability for all activities²

EBITDA rate (as a % of sales)



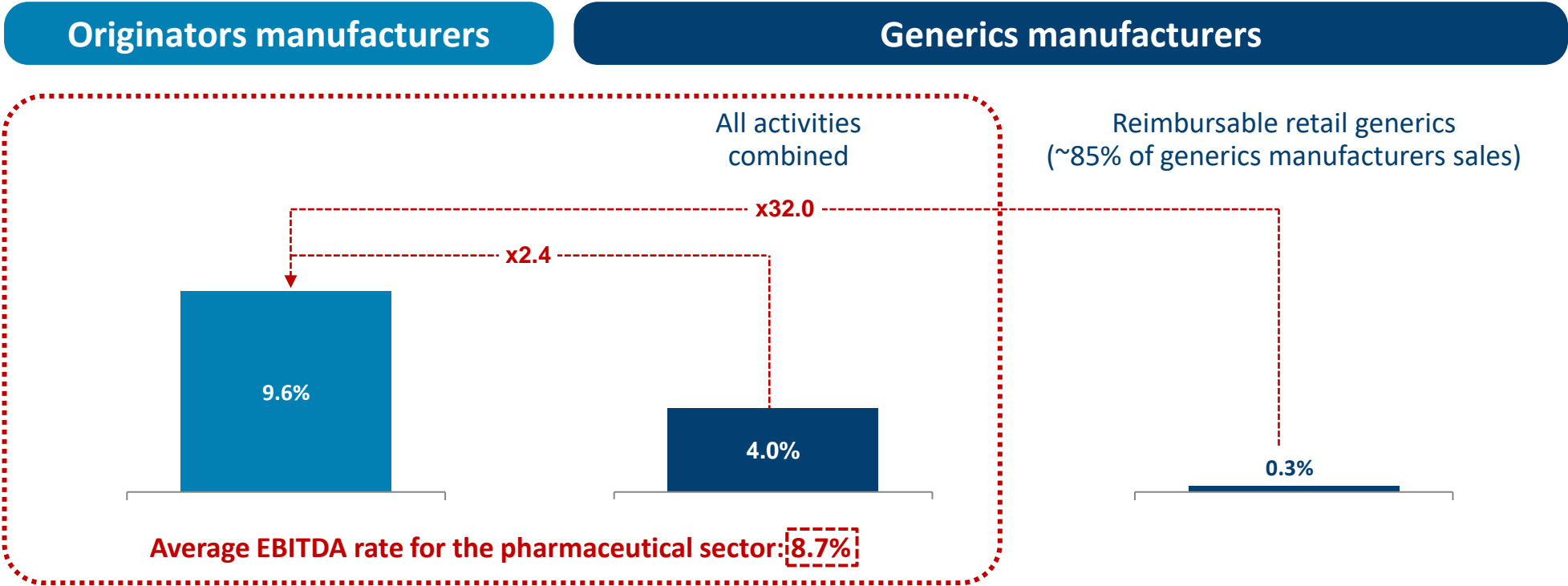
Sources: Statutory accounts of the 7 leaders of the generics market dispensed in retail pharmacies, representing a combined market share of 88% in 2021 – Smart Pharma Consulting analyses

¹ Earning before interest, tax, depreciation and amortization: financial indicator expressing the capacity of a company to generate cash resources solely from its operations – ² Including the profitability of all segments retail and hospitals (i.e., generics, biosimilars, originators, OTC, etc.) – ³ Absence of price cuts and M contribution in 2020 – ⁴ Based on a total M contribution of € 760 M in 2021

In France, the average EBITDA^{1,2} rate of the pharmaceutical industry is ~8.7%, but hides significant disparities between originators and generics manufacturers

Profitability of manufacturers operating in France (2021)

Average EBITDA rates in the pharmaceutical sector – National comparisons



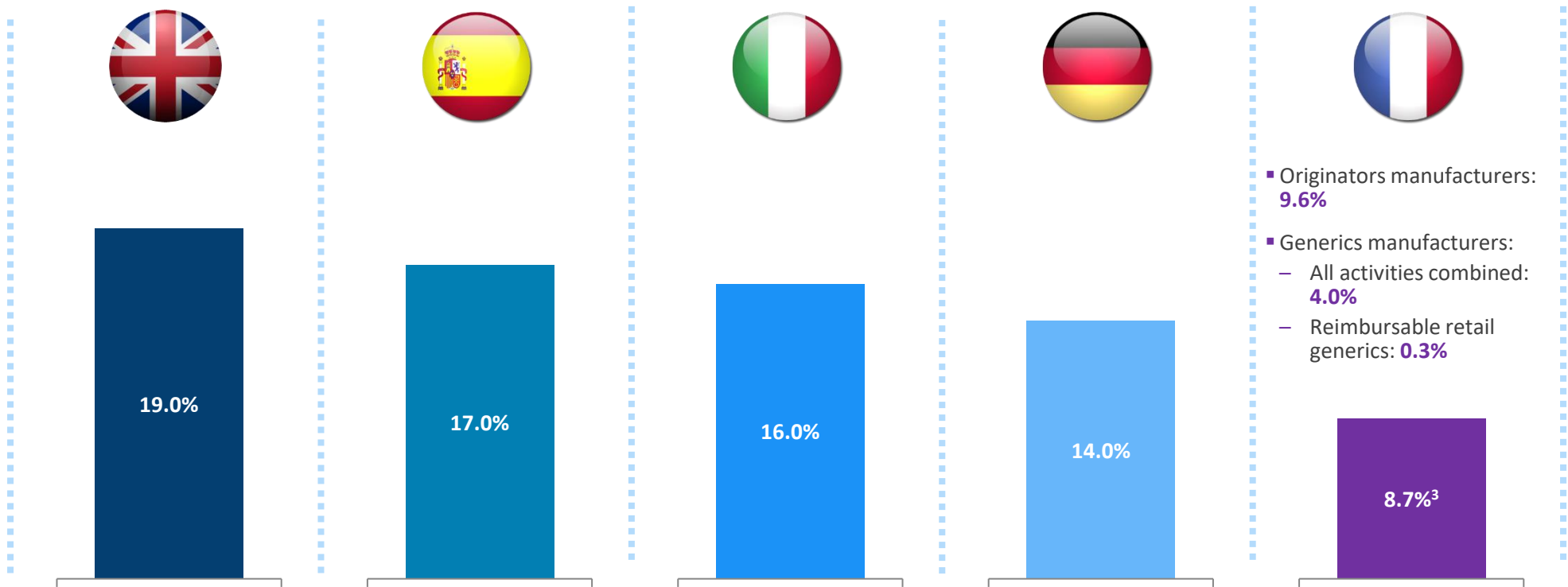
Sources: Statutory and analytical accounts of the 7 leaders of the generics market dispensed in retail pharmacies, representing a combined market share of 88% in 2021 – Insee sector studies – Smart Pharma Consulting analyses

¹ Earning before interest, tax, depreciation and amortization: financial indicator expressing the capacity of a company to generate cash resources solely from its operations – ² Based on a total M contribution of € 760 M in 2021

Among the 5 main European markets, France is the least profitable country for the pharmaceutical sector (and in particular for the generics manufacturers operating there)

Profitability of manufacturers operating in France (2021¹)

Average EBITDA² rates in the pharmaceutical sector – International comparisons



Sources: Statutory and analytical accounts of the 7 leaders of the generics market dispensed in retail pharmacies, representing a combined market share of 88% in 2021 – Insee sector studies – LEEM – Smart Pharma Consulting analyses

¹ Or the most recent year (2018 for the UK, Spain and Italy) – ² Earning before interest, tax, depreciation and amortization; financial indicator expressing the capacity of a company to generate cash resources solely from its operations – ³ Based on a total M contribution of € 760 M in 2021

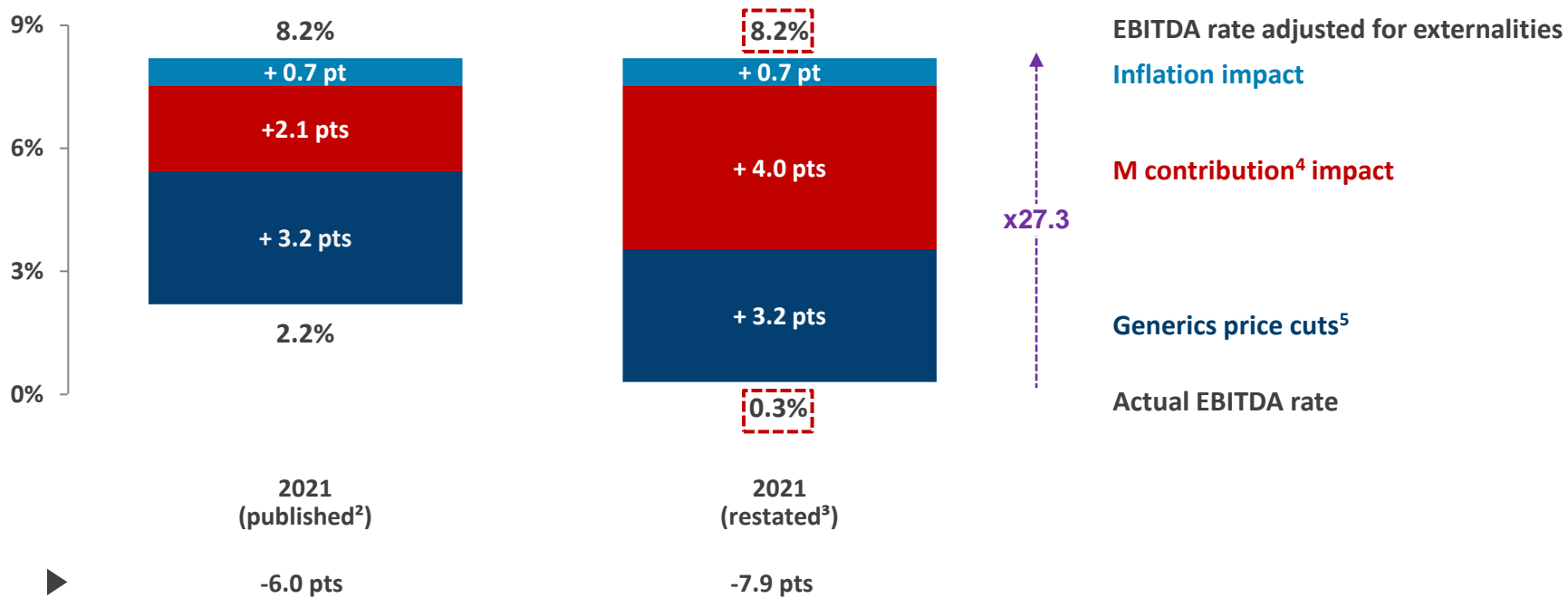
Inflation, M contribution and price cuts contributed to reducing the profitability of reimbursable retail generics from 8.2% to 0.3% of sales

Profitability of generics manufacturers operating in France

Reimbursable retail generics

Impact of externalities on generics manufacturers' profitability (2021)

EBITDA rate (as a % of sales)



Sources: Statutory and analytical accounts of the 7 leaders of the generics market dispensed in retail pharmacies, representing a combined market share of 88% in 2021 – Smart Pharma Consulting estimates and analyses

¹ Earning before interest, tax, depreciation and amortization: financial indicator expressing the capacity of a company to generate cash resources solely from its operations – ² Based on a total M contribution of € 400 M – ³ Based on a total M contribution of € 760 M – ⁴ Before deduction – ⁵ Including carry-over effect

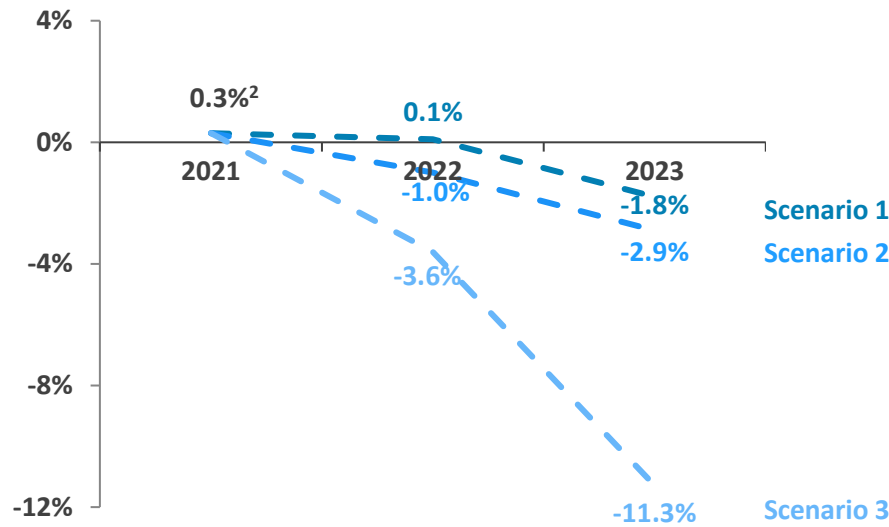
The economic balance of generics manufacturers will be weakened in 2022, and even more so in 2023, with a strong impact of externalities on their level of profitability

Profitability of generics manufacturers operating in France

Reimbursable retail generics

Outlook 2022 – 2023

EBITDA rate² (as a % of sales)



Impact of externalities (in €M)	2021	2022	2023	Scenario
	-234	-240	-296	Scenario 1
		-271	-327	Scenario 2
		-348	-576	Scenario 3

Assumptions 2022 – 2023

Externalities	Scenario	2022	2023	Assumptions
Inflation (including carry-over effect)	#1			<ul style="list-style-type: none"> 2022: inflation of +5.3% (Insee) 2023: inflation of +4.2% (OECD, Ministry of the Economy)
	#2	€ 67 M	€ 124 M	
	#3			
Safeguard clause (before deduction)	#1	€ 93 M		<ul style="list-style-type: none"> ~16% of market share x total M contribution: #1: € 600 M (2022/2023) #2: € 800 M (2022:2023) #3: € 1,300 M (2022) / € 2,400 M (2023)
	#2	€ 124 M		
	#3	€ 202 M	€ 373 M	
Price cuts for generic drugs	#1			<ul style="list-style-type: none"> 2022: CEPS source 2023: same as 2022
	#2	€ 79 M		
	#3			

--- Gemme Estimates / Smart Pharma Consulting

Sources: Statutory and analytical accounts of the 7 leaders of the generics market dispensed in retail pharmacies, representing a combined market share of 88% in 2021 – Insee (2022) – OECD (2022) – Government communications (2022) – Smart Pharma Consulting estimates and analyses

¹ Earning before interest, tax, depreciation and amortization: financial indicator expressing the capacity of a company to generate cash resources solely from its operations – ² Based on a total M contribution of € 760 M

The more the share of generics grows, the more Social Security makes savings and the higher is the contribution M which significantly impacts the margin of market players

Generics: Current situation

> € 2 B
of savings
generated
per year

- With a **penetration rate of 84%** of the generics directory
- Generic drugs allow substantial **savings** to the Social Security every year....
- ... which can be used to reimburse more expensive **innovative** treatments

€ 237 M
Impact of
externalities¹
incurred in 2021

- With a **€ 118 M contribution**, **€ 96 M price cuts** and **€ 23 M inflation**, the economic balance of generic manufacturers has never been so fragile as in 2021
- ... to the point of generating **losses**, for many of them, likely to settle over time

~0.3%
Average EBITDA
rate in 2021

- **Reimbursable retail generics have almost nil and much lower operating margins** than:
 - **Originator manufacturers in France** (9.6% of EBITDA)..
 - ... and in **Europe**:
 - ✓ ~19% in the UK
 - ✓ ~17% in Spain
 - ✓ ~16% in Italy
 - ✓ ~14% in Germany

The increasingly precarious situation of generic manufacturers requires reconsidering price reductions and the safeguard clause

Generis: 2022 – 2023 perspectives

€ 191 M

Cumulated impact
of inflation
over 2022 - 2023

- With **inflation rates** estimated at **+5.3%** for **2022** and **+4.2%** for **2023**...
- ... retail reimbursable generics manufacturers will be strongly impacted on their **costs**:
 - Of **goods sold** (+ € 149 M)
 - Of **staff** (+ € 27 M)
 - Of **distribution** (+ € 14 M)

€ 158 M

Impact of
price cuts
over 2022 – 2023

- If the **price cuts** decided in the **LFSS¹** are **maintained in 2023** ...
- ... they are likely to have a major **deleterious impact** on the **profitability** of generics manufacturers
- This impact has been estimated at **€ 79 M** per year, i.e., **€ 158 M** over **2022-2023**

-1.8%² to

-11.3%³

EBITDA rate
for 2023

- The **fragility** of generics manufacturers observed in 2021 is likely to **deteriorate** in **2022**, and **even more** so in **2023** given the:
 - **Inflation**
 - **Price cuts**
 - **M contribution**

As part of its "emergency plan for generic and biosimilar medicines",
 Gemme proposes to revise the fiscal and economic environment of mature medicines

Generics: Gemme proposals

Revision of the tax environment for mature drugs

- Revision of the **scope and calculation** of the **safeguard clause**¹
- Revision of **M amount** for 2022
- Introduction of a **mechanism for rebasing the value** of M for the following year

Moratorium on price reductions for mature drugs for 2023

- **Protection** of the already **degraded economy** of generics:
 - **Tensions** in terms of **supply**
 - **Weakening** of the **industrial tool**
 - **Loss of attractiveness** for the French market

Integration of inflation in the price of least expensive drugs

- **Revision of the price** of drugs whose ex-factory price is $\leq \text{€ } 5\text{€ / pack}$ or $\leq 0.12 \text{ € par tablet}$ considering **inflation** (estimated at 5% for 2022)
- **Expected impact** of this measure for **Social Security: € 185 M**

Setting up of a floor price

- Setting up of a **floor price** (€ 0.14 € / tablet)
- This floor price would be:
 - **Registered** in the **Public Health Code**
 - Fixed under the **framework agreement** between **CEPS and LEEM**

