

The French Retail Generics Market

Market Insights

Situation Analysis

&

2027 Perspectives

Smart Pharma Consulting has developed an expertise – second to none – regarding the generics market in general and the French generics market in particular, as shown in this position paper

Introduction

Smart Pharma Consulting Expertise regarding the French generics market

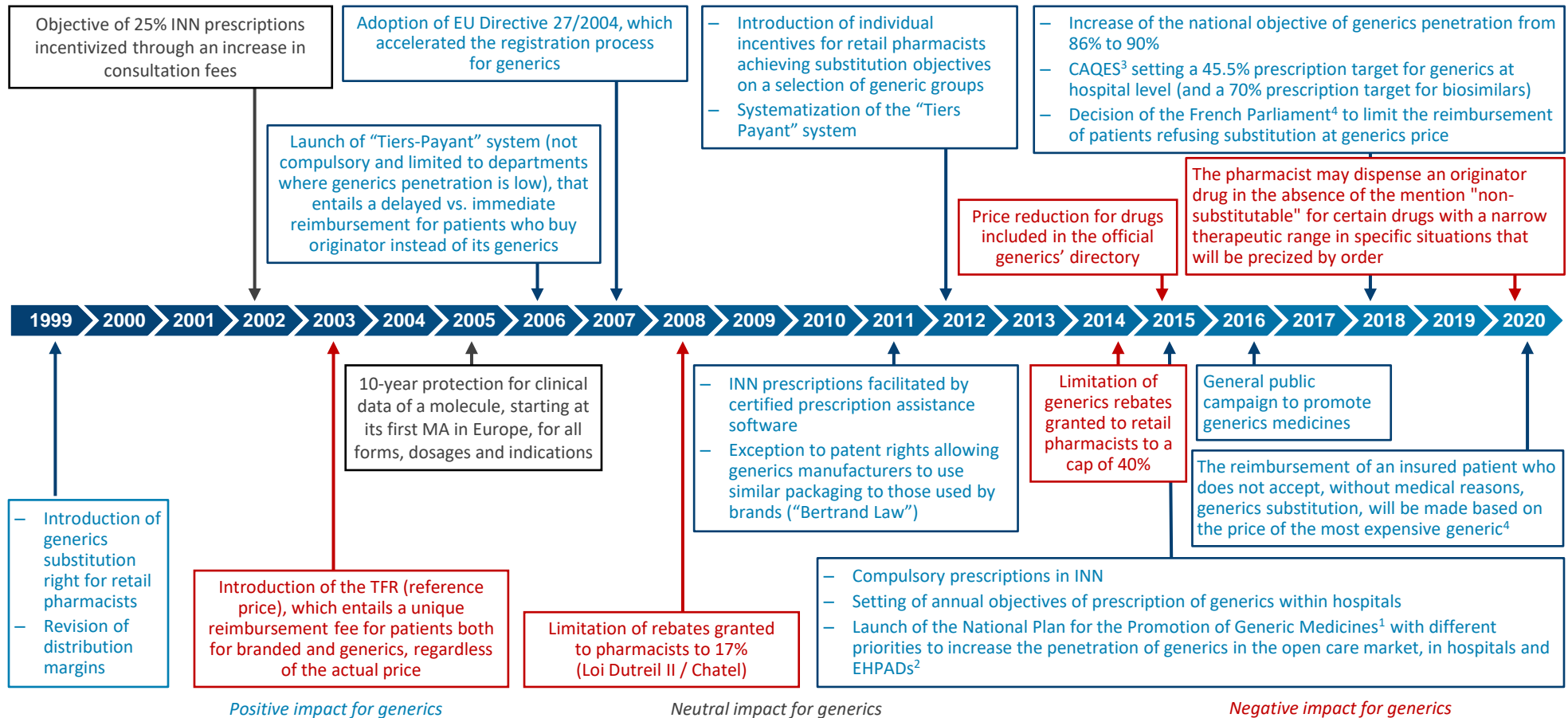
- Operational experience of one of the consultants as general Manager France for Novartis' generics business
- Strategic and management missions carried out for 16 generics companies in France and abroad:
 - Accord Healthcare – Arrow (Aurobindo) – Biogaran (Servier) – Dr Reddy's – EG Labo (Stada) – Gedeon Richter
 - Glenmark – Hospira (Pfizer) – Polymedic – Sandoz – Sothema – Teva – Viatris – Wockhardt – Zentiva – Zydus
- Several position papers and reports about the French generics market
- Several articles published regarding generics related issues:
 - Entering the French generics market (1997)
 - Can generics really help to curb French healthcare costs? (1999)
 - Lighting fire from wet timber in French generics market (2001)
 - How bright is the future for generics? (2003)
 - Barriers to substitution (2005)
 - What is the value of authorized generic agreements? (2006)
 - What future for the French retail generic market? (2015)

Context – Objective – Methodology

- The development of retail generics is a major lever to help the French government contain the growth of the drug costs reimbursed by the National health Insurance Fund
- This position paper analyzes the current business environment of the French retail generics market and...
- ... estimates its 2027 gross and net sales perspectives
- To do so, the consultants have capitalized on their long experience and strong expertise re. this strategic segment

Since the substitution right has been granted to retail pharmacists in 1999, the different governments have introduced several measures to favor the development of generics

Main governmental measures related to retail generics (1999 – 2020)



The prices, margins and level of rebates are regulated by the CEPS (drug pricing committee) throughout the value chain of the reimbursable products, either originators or generics

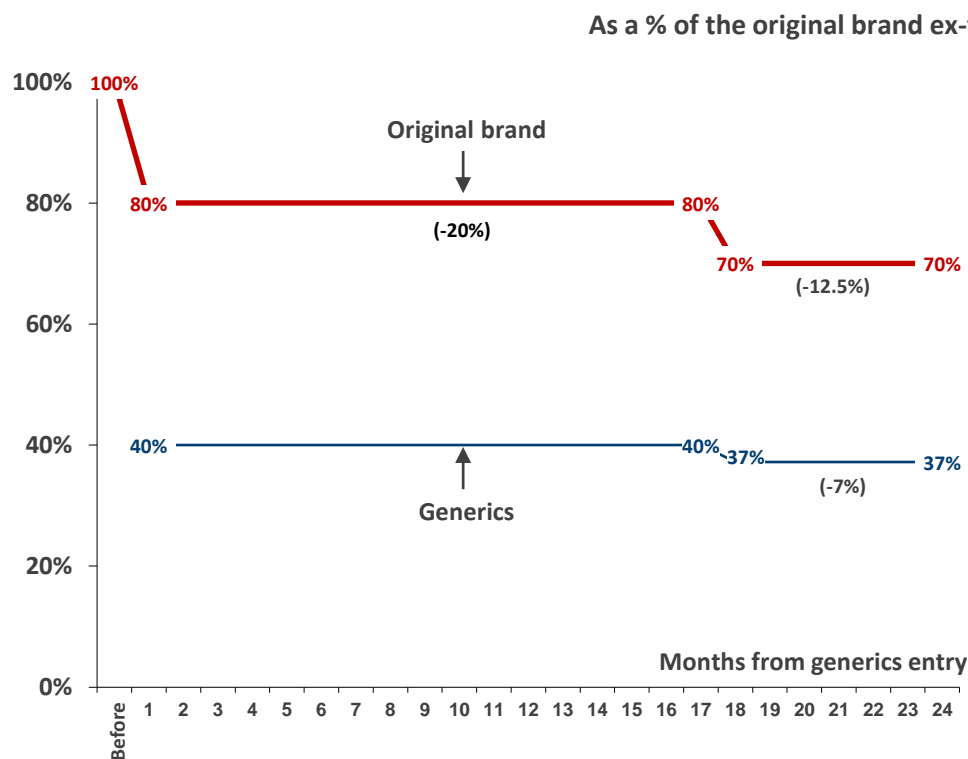
Prices, margins and rebates for reimbursable drugs

	Originator without TFR ¹	Originator with TFR	Generic without TFR	Generic with TFR
Ex-factory price	<ul style="list-style-type: none">Price negotiated / set by the CEPSGenerics are priced 60% below originator price at patent expiryOriginator price is cut by 20% after generics entry or at patent expiry			
Wholesalers' margins	<ul style="list-style-type: none">Minimum of € 0.30 per pack if ex-factory price below € 4.336.93% of ex-factory price if ex-factory price from € 4.33 to € 468.970% beyond € 468.97, representing a maximum of € 32.50 margin per sold unit			
Pharmacists' margins	<ul style="list-style-type: none">Variable margin:<ul style="list-style-type: none">10.0% of ex-factory price below € 1.927.0% from € 1.92 to € 22.905.5% from € 22.91 to € 150.005.0% from € 150.01 to € 1,930.000% above € 1,930.00Dispensing fees (VAT excluded):<ul style="list-style-type: none">€ 1.00 per pack (for monthly packs)€ 2.70 per pack (for quarterly packs)€ 0.50 per prescription including at least 1 reimbursable drug€ 3.50 for specific drugs (e.g., immunosuppressive drugs)€ 1.55 if the patient is under 3 years or over 70 years old€ 0.30 per prescription with at least 5 medicines	Margin in absolute terms identical to the corresponding originator		Calculation identical to the originator's one
Pharmacists' rebates ²	<ul style="list-style-type: none">Maximum legal rebate: 2.5% of ex-factory price	<ul style="list-style-type: none">Maximum legal rebate: 40% of ex-factory price, since September 2014 (17% before)		
	<ul style="list-style-type: none">Possibility to add up to 100% of the wholesaler margin in case of direct sales			

In the absence of reference price (TFR), the original brand can preserve 80% of its initial ex-factory price, which further decreases to 70% after 18 months

Price revision of genericized and generics products

Without reference price (TFR)



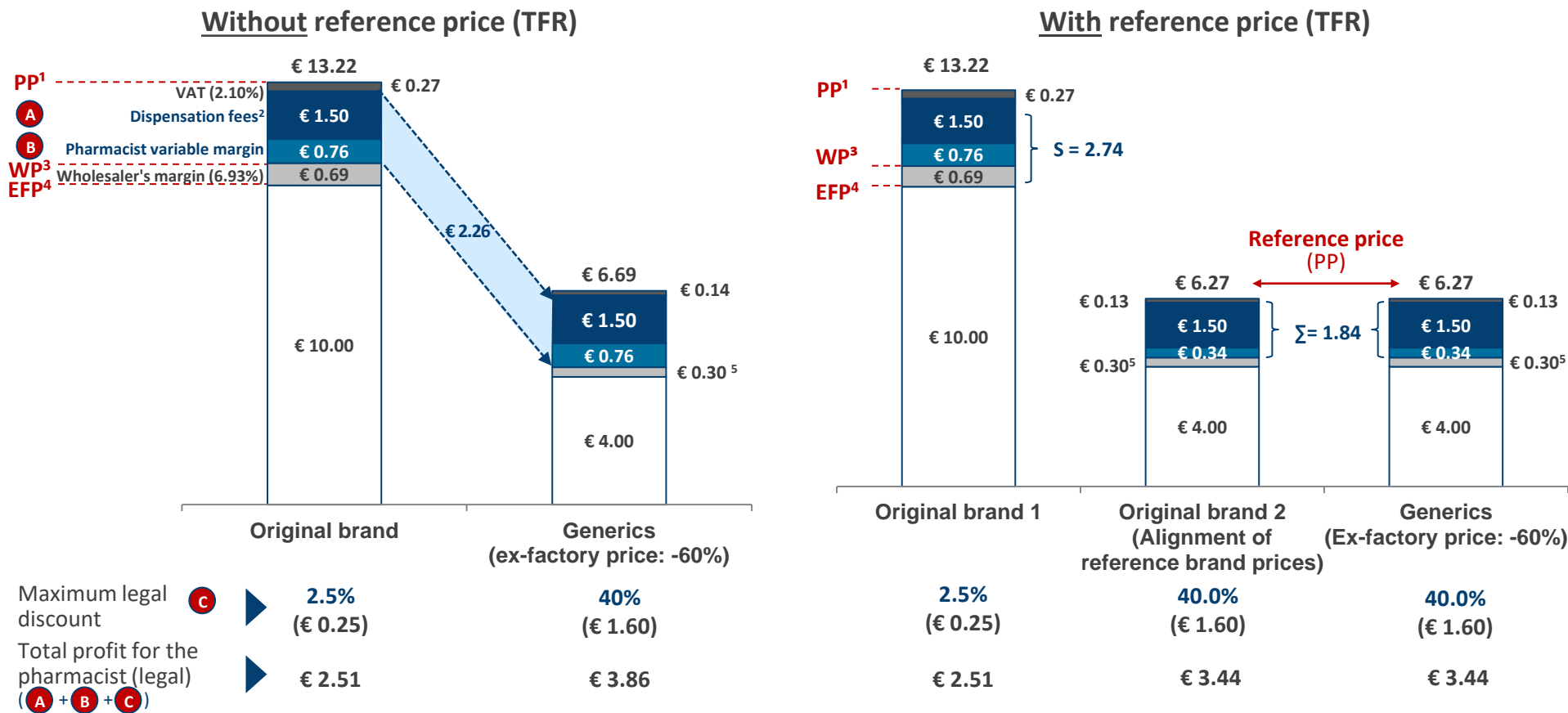
With reference price (TFR)¹



Once the patent of an original product has expired, a price cut of 20% is applied by the CEPS (drug price committee), even if there is no generics

The levels of margins and rebates set by the CEPS (drug pricing committee) for drugs sold on the retail market contribute to regulate the evolution of cost of reimbursed drugs

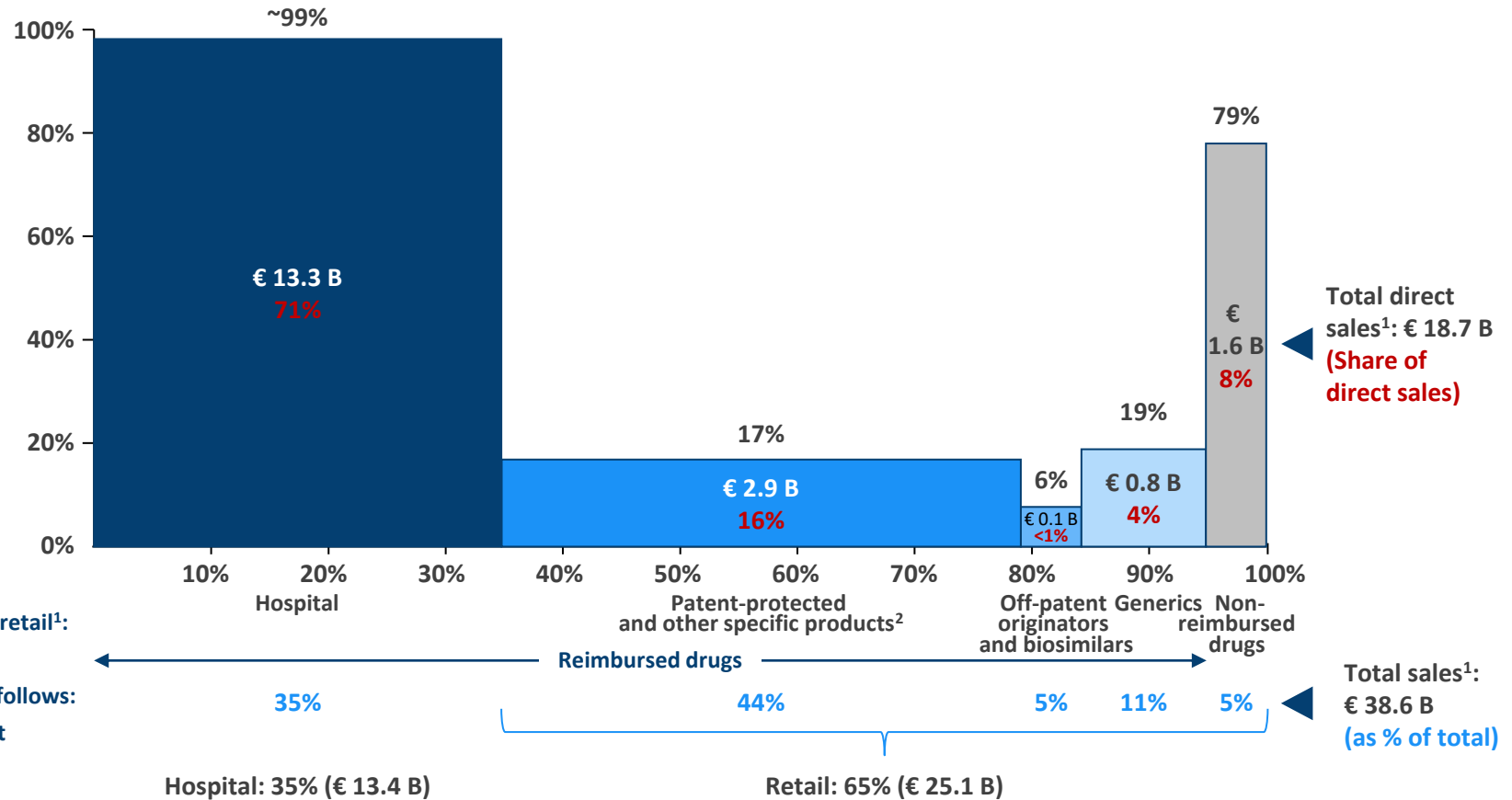
Legal margins and discounts for reimbursed drugs on the retail market



~19% of generics retail sales are directly distributed by pharma companies, through agents (pre-wholesalers)

Share of direct sales by segment (2022)

Direct sales
as % of total sales¹

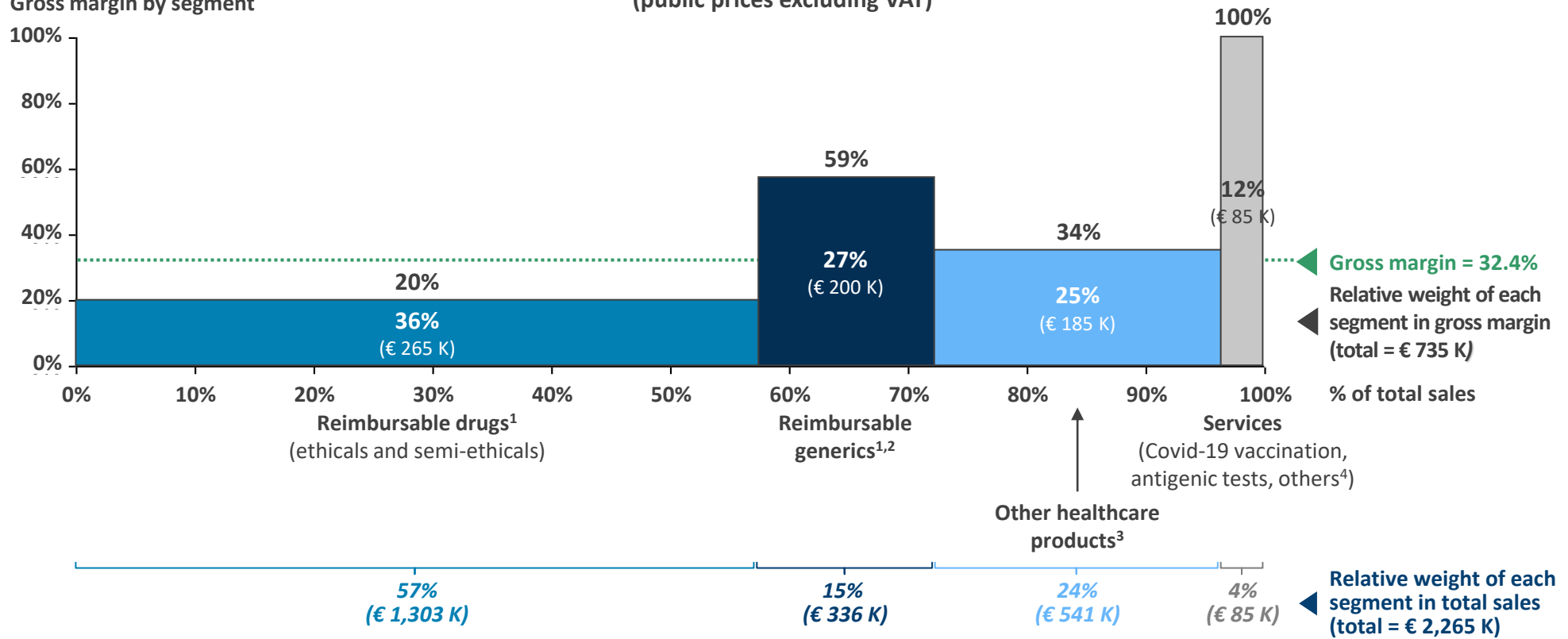


In 2022, generics accounted for ~15% of the retail pharmacies sales on average, and for ~27% of their gross margin, knowing that pharmacists work in general with two generics companies

Weight of generics in the economic structure of retail pharmacies (2022)*

Average annual turnover of a retail pharmacy in 2022: € 2,265 K
 (public prices excluding VAT)

Gross margin by segment



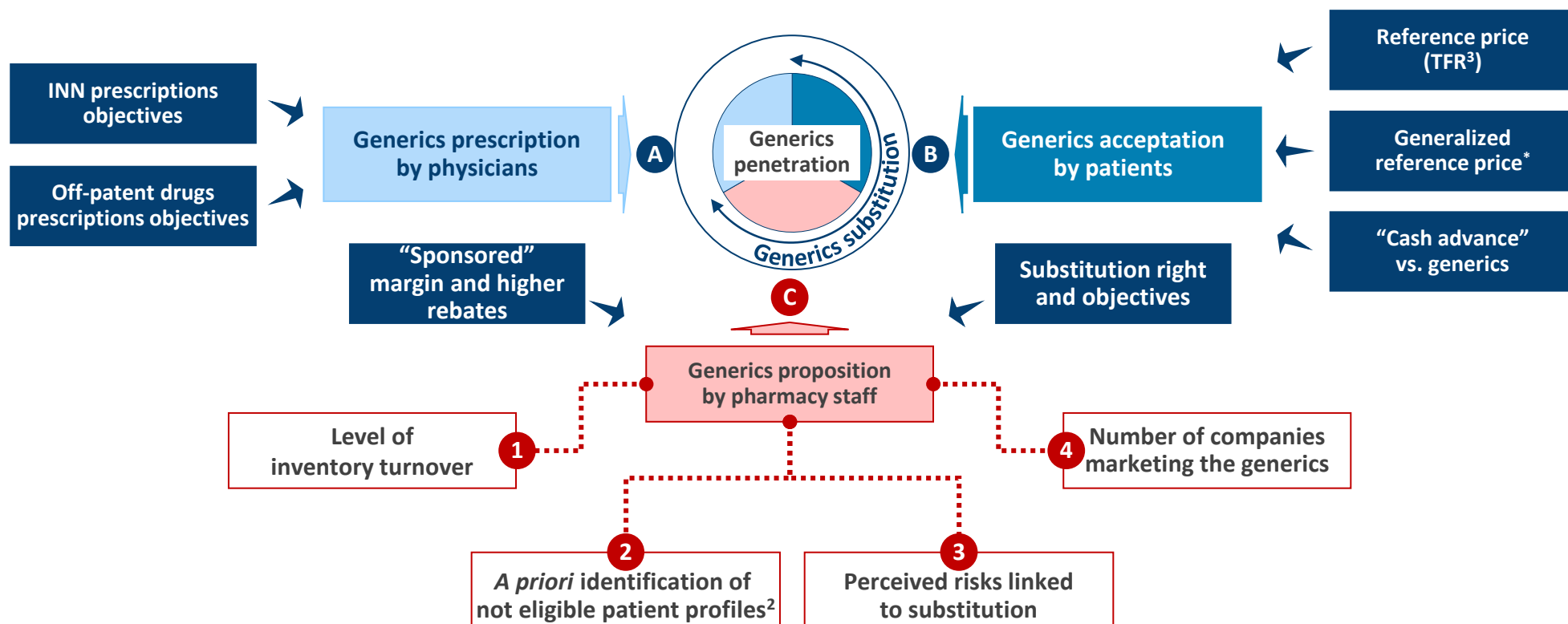
* Data estimated based on a sample of 1,807 retail pharmacies

Sources : CGP Experts Comptables (2023) – External interviews with accounting experts (July 2023) – Smart Pharma Consulting estimates

¹ Including dispensing fee – ² Including commercial cooperation with generic companies – ³ Including OTC and “lifestyle” Rx products, medical devices, food supplements, para-pharmacy products, etc. – ⁴ Remuneration for services corresponding to public health objectives (ROSP), new missions, etc.

Generics penetration is facilitated by INN¹ prescription and substitution, both of which are enhanced by a favorable support from health authorities

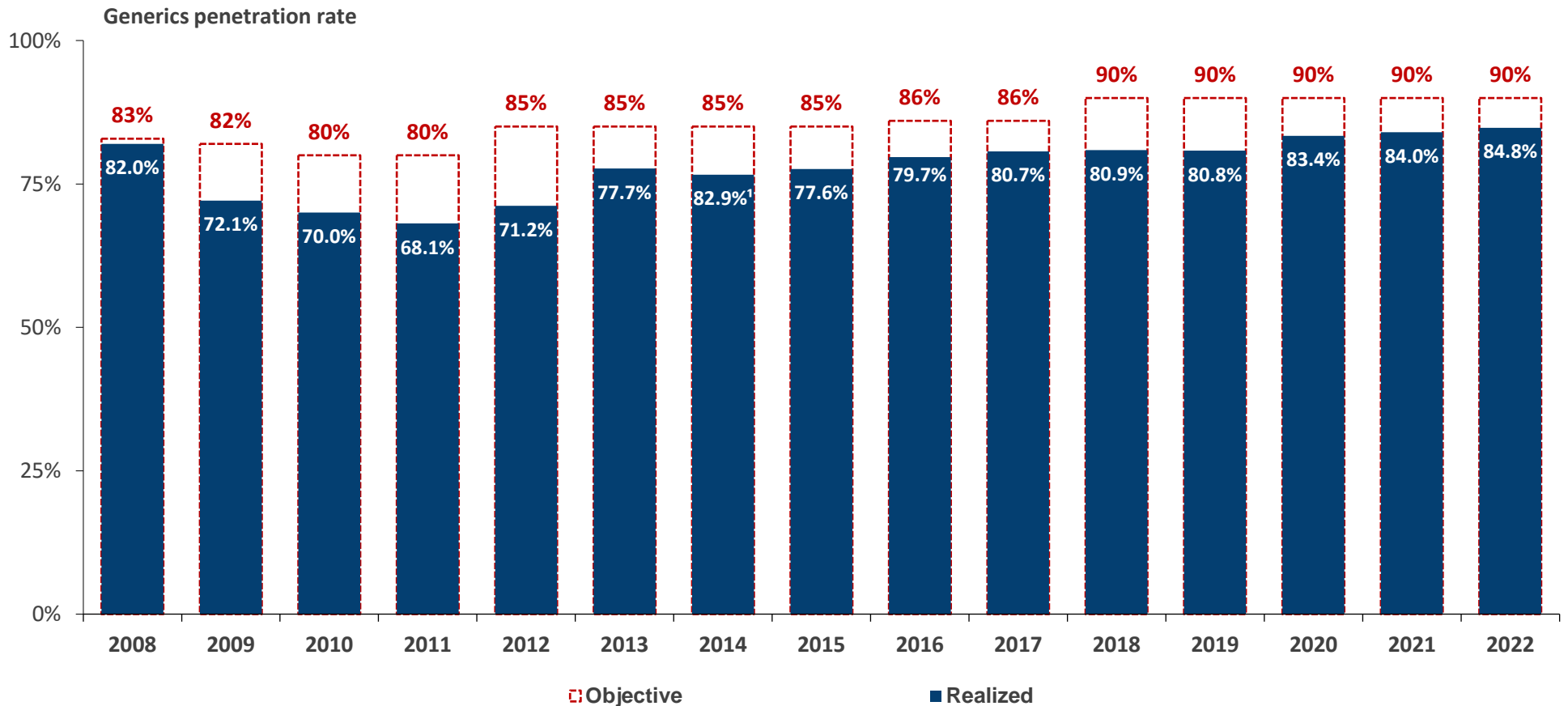
Key drivers of generics penetration on the retail market



* Two years after the first generic get its price published, the originator will be reimbursed, based on the price of the most expensive generic. The price difference – if any – will be supported by the patient, unless he has a valid medical reason to refuse the substitution

Retail pharmacists receive every year a national substitution target set by the National Health Insurance Fund which has never been achieved so far

Objectives and realized substitution rates (2008 – 2022)



Sources: 13th and 14th amendments to the Generics delivery Convention (November 17th, 2019 and August 20, 2020) – GERS dashboard (2008 – 2022) – Smart Pharma Consulting analyses

Substitution of original drugs by their generics results from an interaction between pharmacy teams and patients

Drivers and limiters of generics substitution by retail pharmacists

Drivers of generics substitution

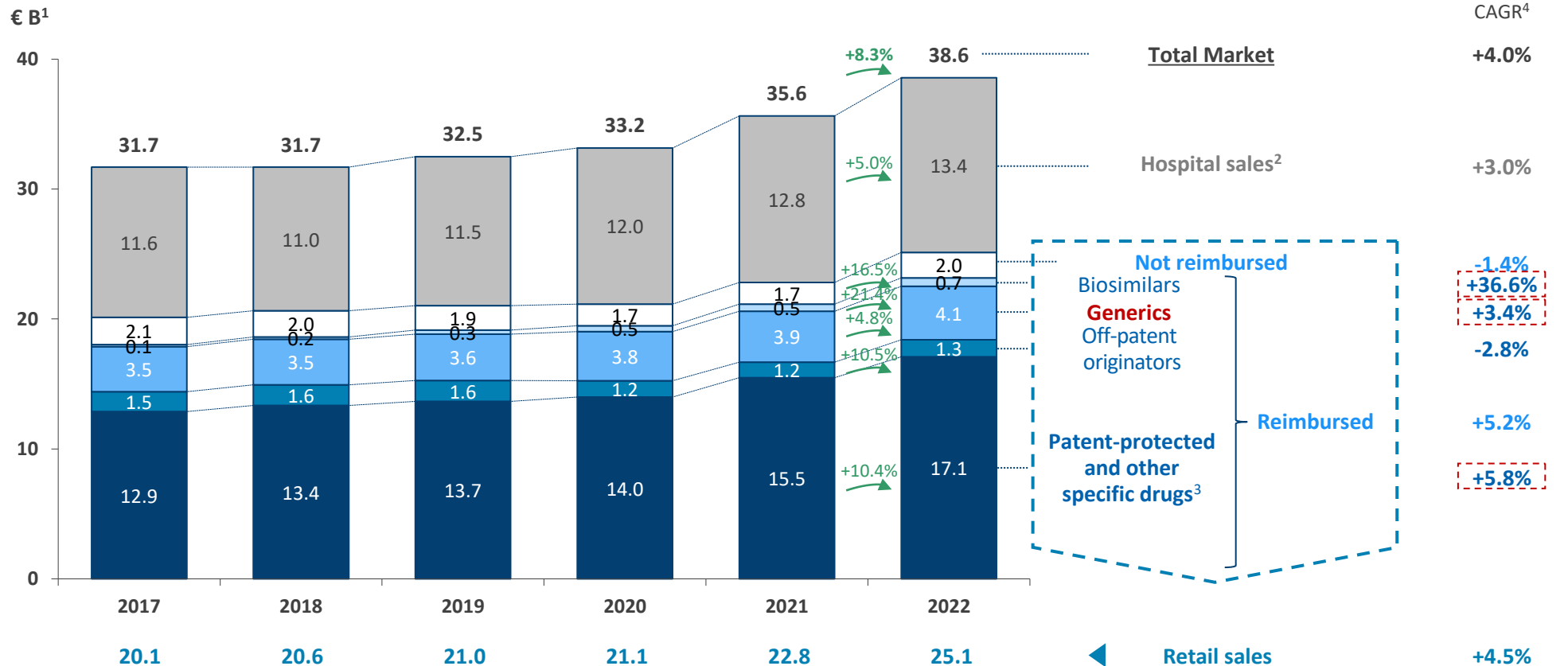
- Information campaigns from the National Health Insurance Fund to inform patients about generics
- Out-of-pocket expenditure for patients refusing generics substitution without medical reasons¹
- “Cash advance vs. generics” system
- Retail pharmacy substitution objectives for pharmacists
- INN prescriptions objectives within or outside the ANSM directory such as the ROSP²
- “DAM³” calls to medical offices
- Patients’ information on their pathology: it is easier to convince patients who are already aware of their disease and of the associated treatments to try generics
- Inducement to prescribe generics for initiation prescriptions in hospitals or discharged patients to increase patients’ confidence in generics
- Creation of a “hybrid” label to facilitate substitution

Limiters of generics substitution

- ANSM warnings / recommendations
- Complexity of the pathology (e.g., opiates dependence, immunosuppression, epilepsy, etc.)
- Small share of INN prescriptions
- “Non substitutable” on scripts
- Limited number of generic companies
- Late arrival on the generics market (patients more worried and reluctant to generic substitution when treatment with an original brand was initiated a long time ago)
- Low inventory rotation in pharmacies
- Low proposal of generics by pharmacists
- Refusal of patients
- No correspondence of dosages / different chemical forms between generics and original brands
- Existence of different generic groups for a single molecule
- Protection of an indication

Since 2017, spending on drugs has been mainly driven by patent-protected drugs, generics and biosimilars delivered in retail pharmacies

Evolution of drugs sales by segment (2017 – 2022)

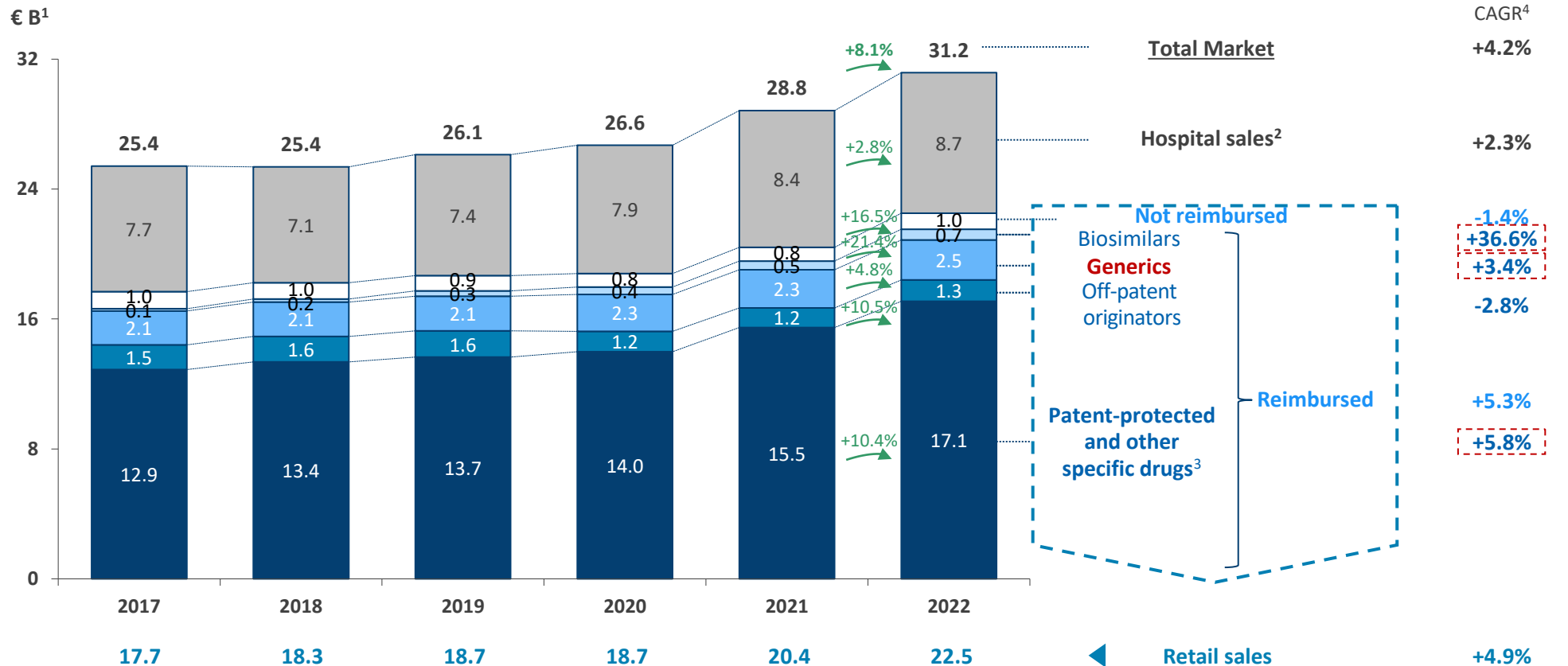


Sources: GERS dashboards –
 Smart Pharma Consulting estimates

¹ Constant ex-factory prices, before rebates and taxes – ² Including hospital sales of biosimilars, products invoiced on top of “T2A” and retroceded 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 2017-2022

The retail generics market has been estimated at € 2.5 B in net price value, that is 39% lower than its list price value, considering the average discounts granted to retail pharmacies

Evolution of drugs sales by segment (2017 – 2022)



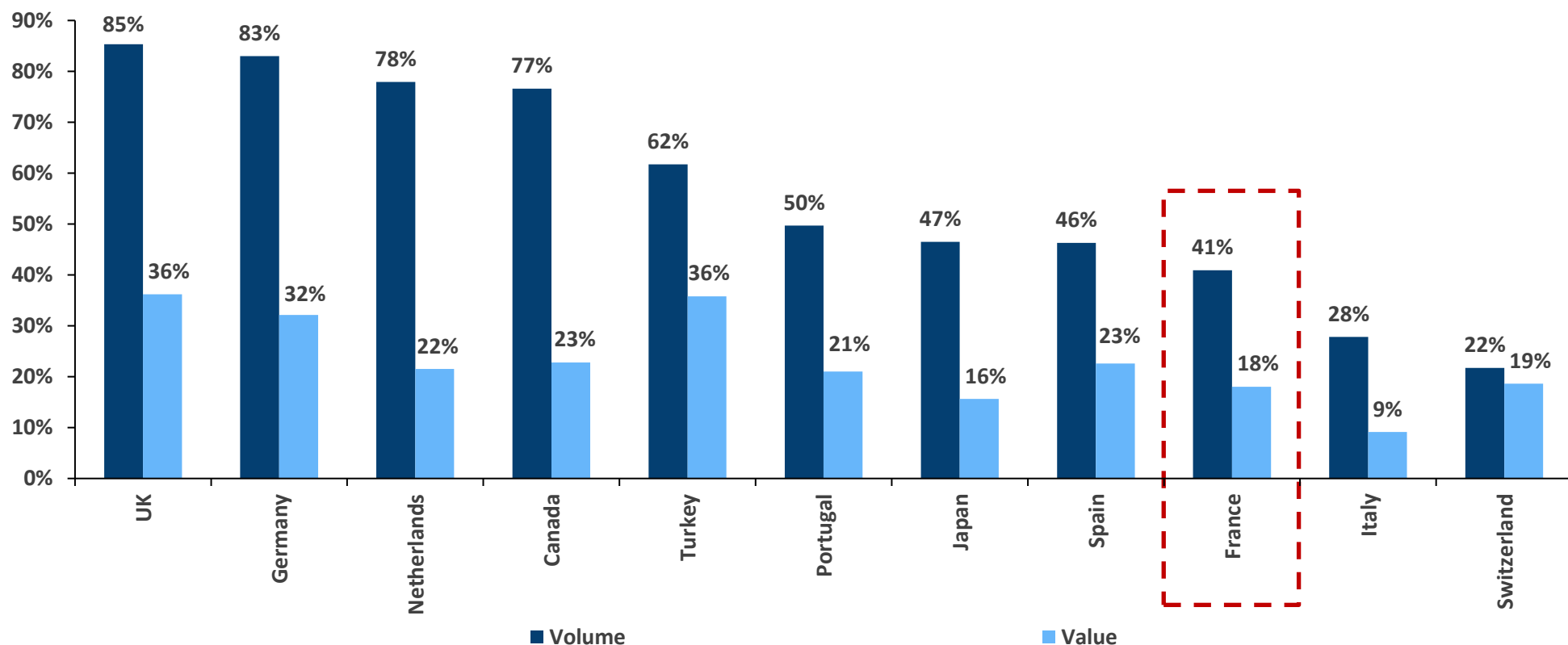
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¹ Constant ex-factory prices, after estimated rebates and before taxes – ² Including hospital sales of biosimilars, products invoiced on top of “T2A” and retroceded medicines –
³ Sales of drugs whose patent has not expired and of other specific products (e.g., calcium, sodium, potassium, paracetamol) – ⁴ Compound annual growth rate 2017- 2022

With a generics penetration rate of ~41% of the retail reimbursed market in volume (and ~18% in value), France is below most OECD countries

Generics penetration in the retail reimbursed market – International comparisons (2022¹)

% of retail reimbursed drugs sales

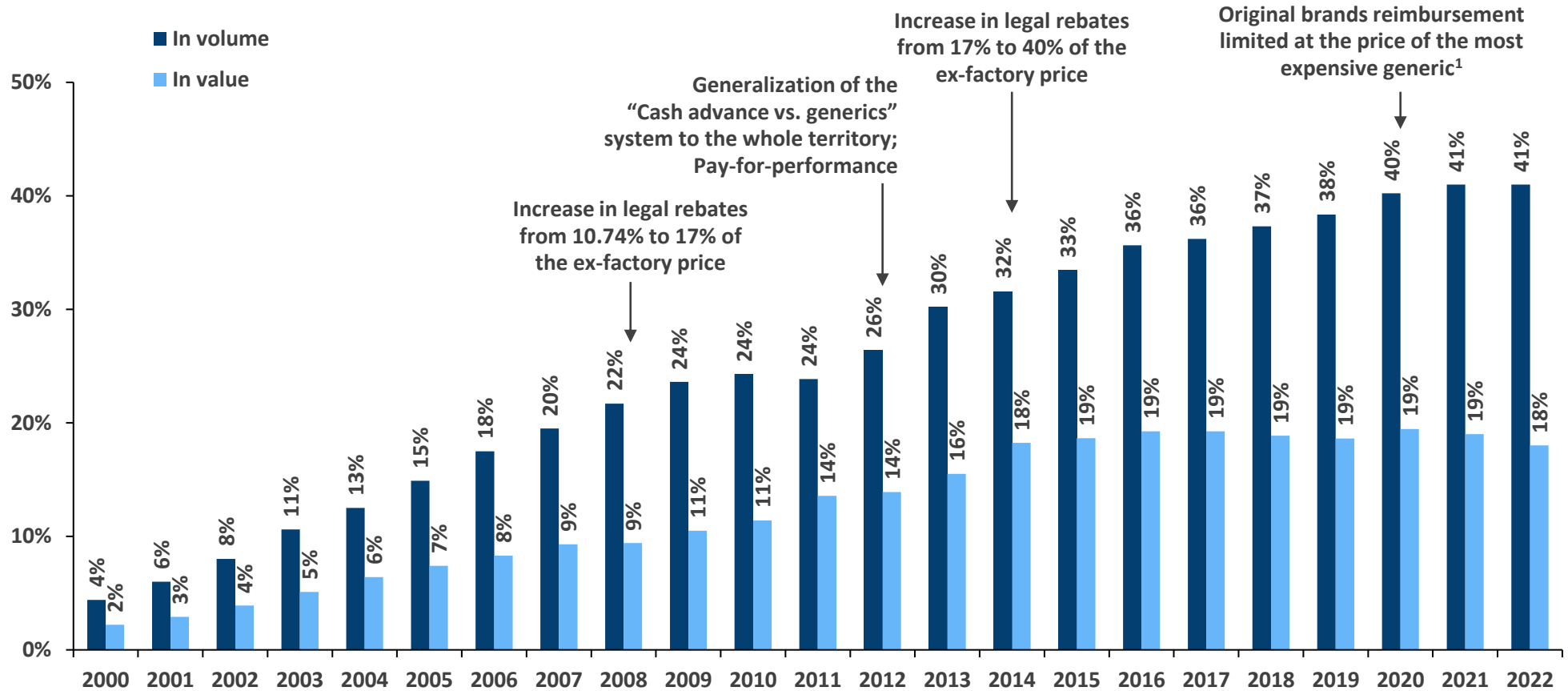


Sources: OECD Health Statistics (March 2021) – GERS Dashboard for France (2022) – Smart Pharma Consulting analyses

¹ Or latest data available

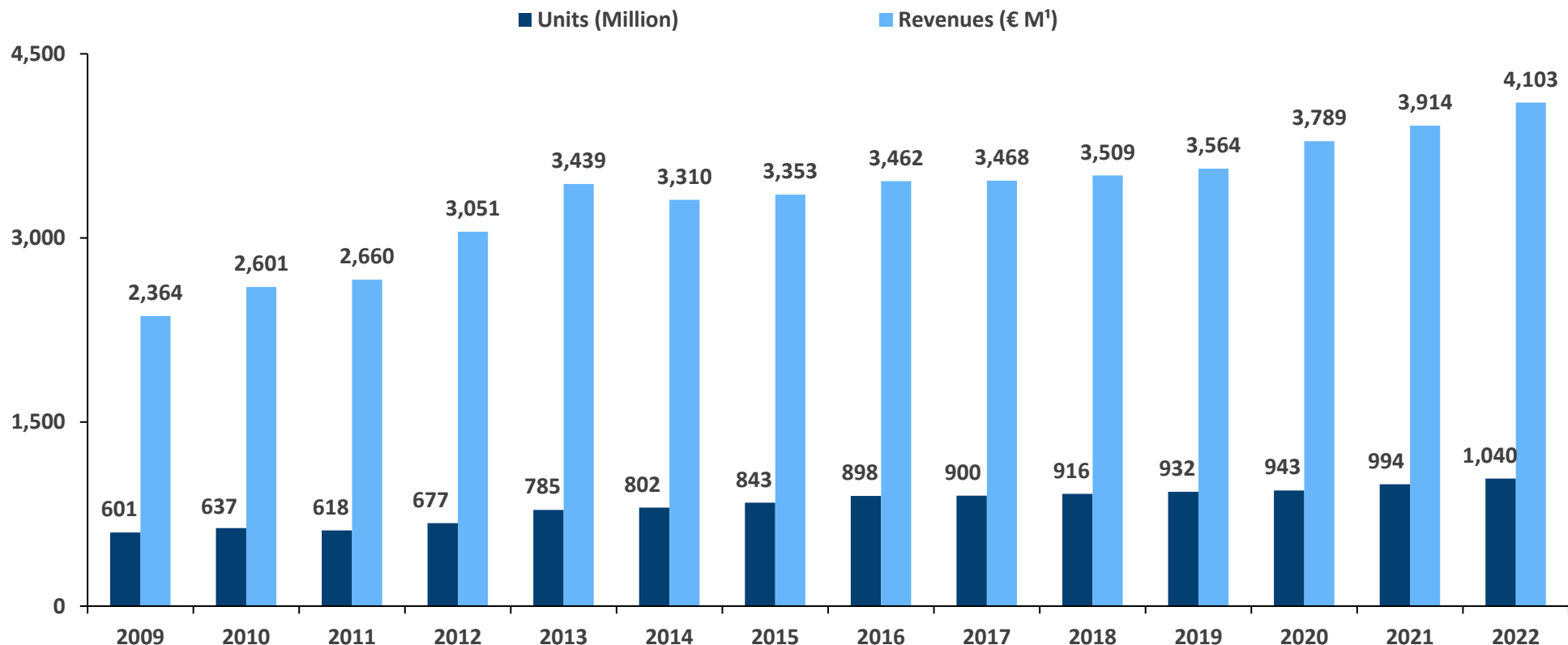
The penetration rate of generics in the retail reimbursable market in volume has been constantly growing since 2000

Evolution of generics penetration in the retail reimbursable market (2000 – 2022)



**In 2022, sales of reimbursable generics reached € 4.1 B
and more than 1 B units in the retail market...**

Evolution of reimbursable generics in the retail market (1/3)

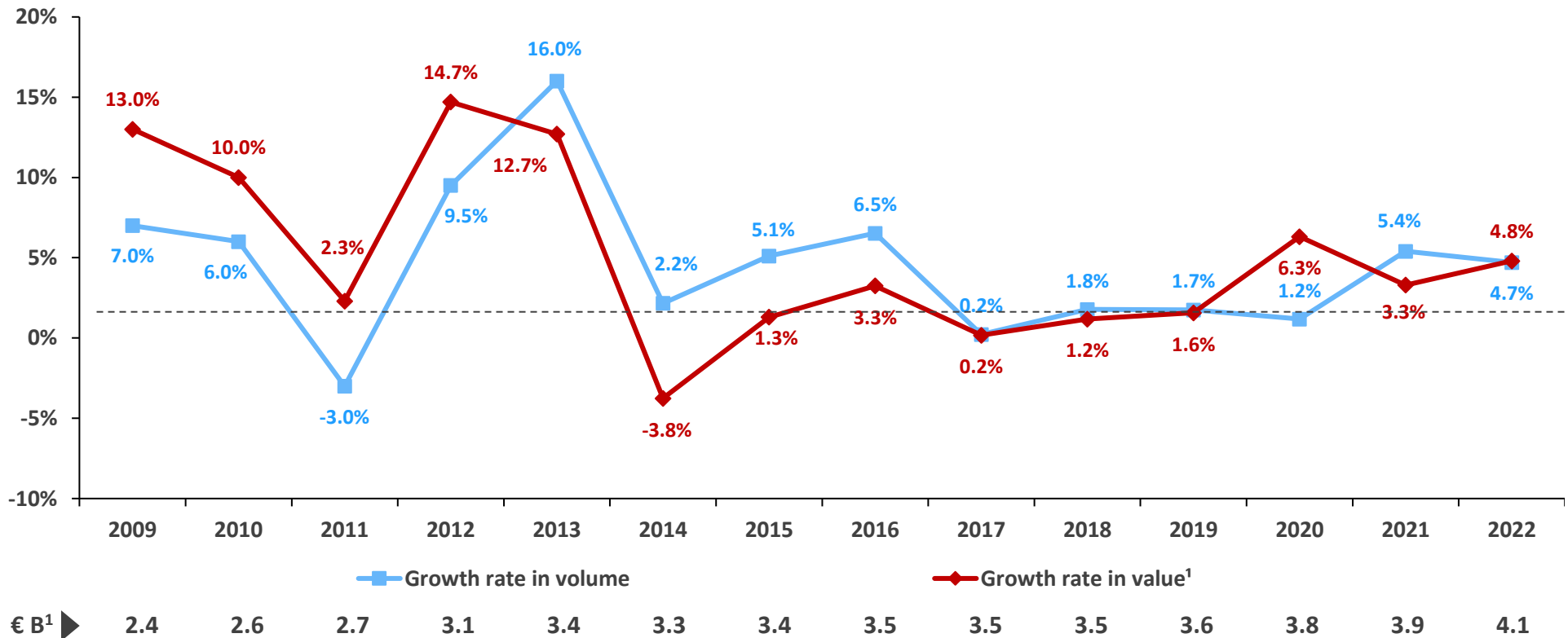


The share of the exploited Generics Directory on the retail reimbursable market in volume represented 48.2% in 2022

... with an annual progression similar in value (+4.8%)
 and in volume (+4.7%), for the first time since 2019

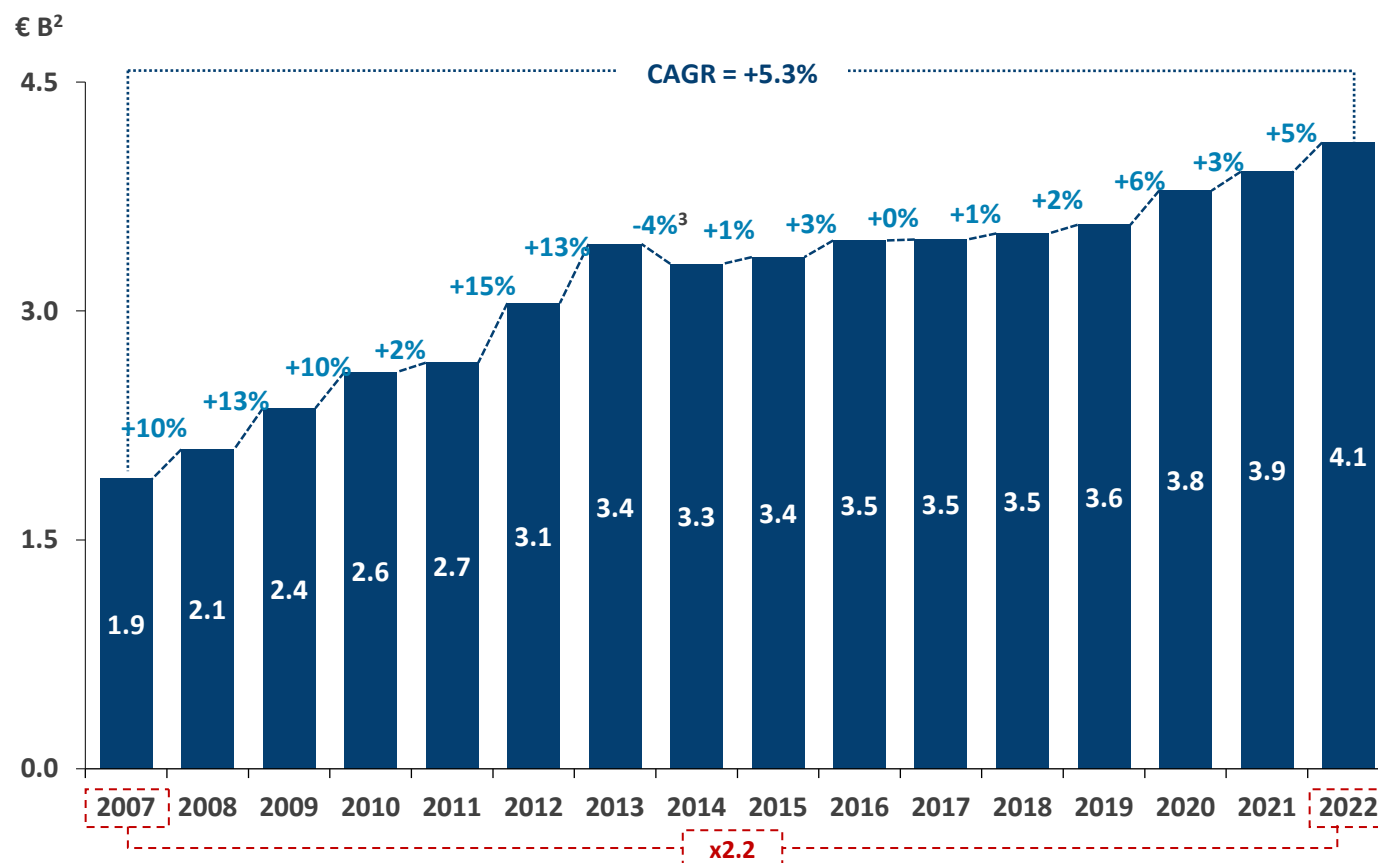
Evolution of reimbursable generics in the retail market (2/3)

% of growth (vs. year-1)



In value terms, the retail generics market growth has slowed down since 2013 due to regular price cuts decided by health authorities and applied by the CEPS¹

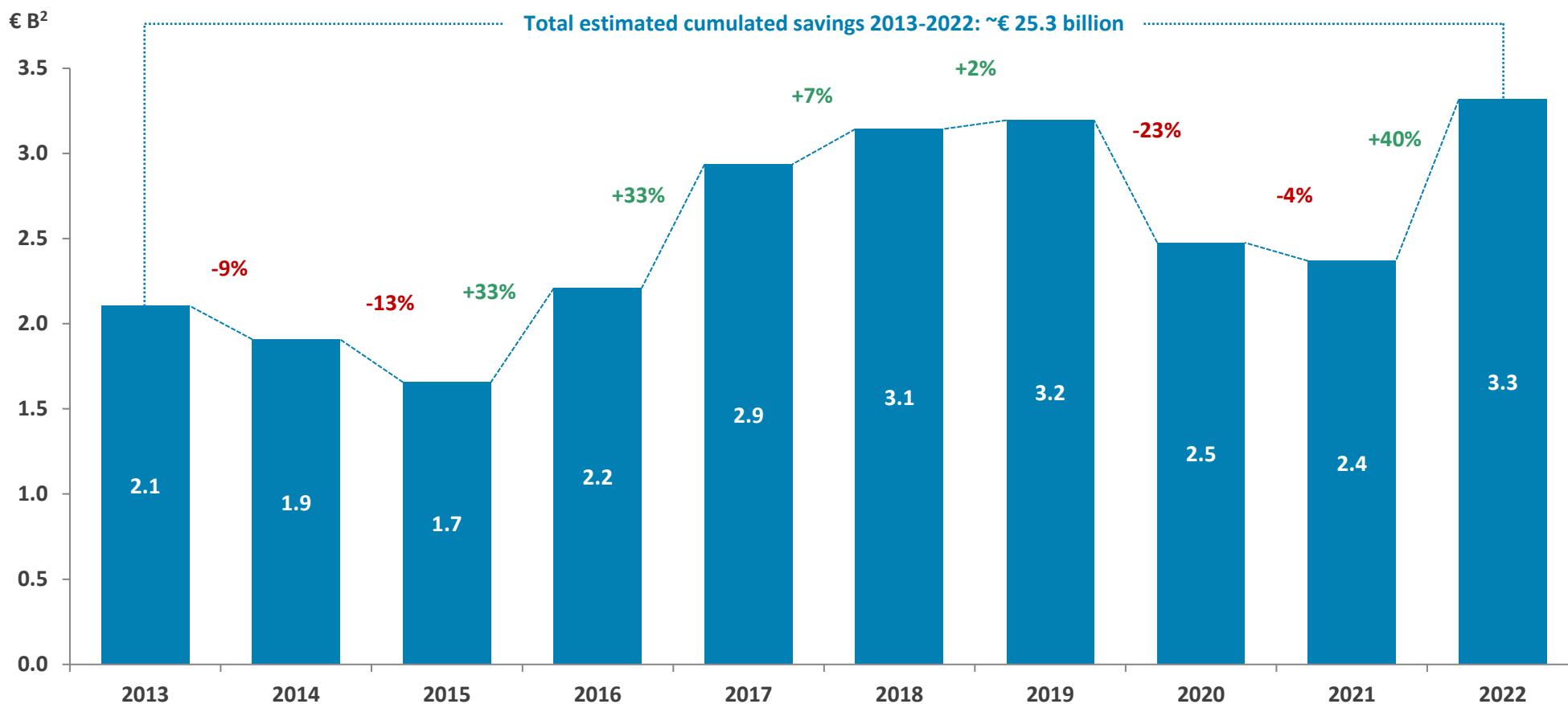
Evolution of reimbursable generics in the retail market (3/3)



- After a slow-down in 2011, the sales of the generics market have been re-boosted by governmental measures introduced since 2012:
 - Increase of the national objective of average generics penetration
 - Introduction of individual incentives for pharmacists achieving substitution objectives on a selection of generic groups
 - Generalization of the “Tiers Payant” system, which exempts from upfront payment patients accepting generic substitution
 - From January 2020, limitation of the reimbursement of patients refusing substitution (without medical justification) at the generic highest price⁴

Estimated savings generated by generics reached ~€ 3.3 billion in the year 2022 and accounted for a cumulated ~€ 25 billion over the 2013-2022 period for the National Health Insurance Fund

Estimated¹ savings generated by retail generics for the National Health Insurance Fund



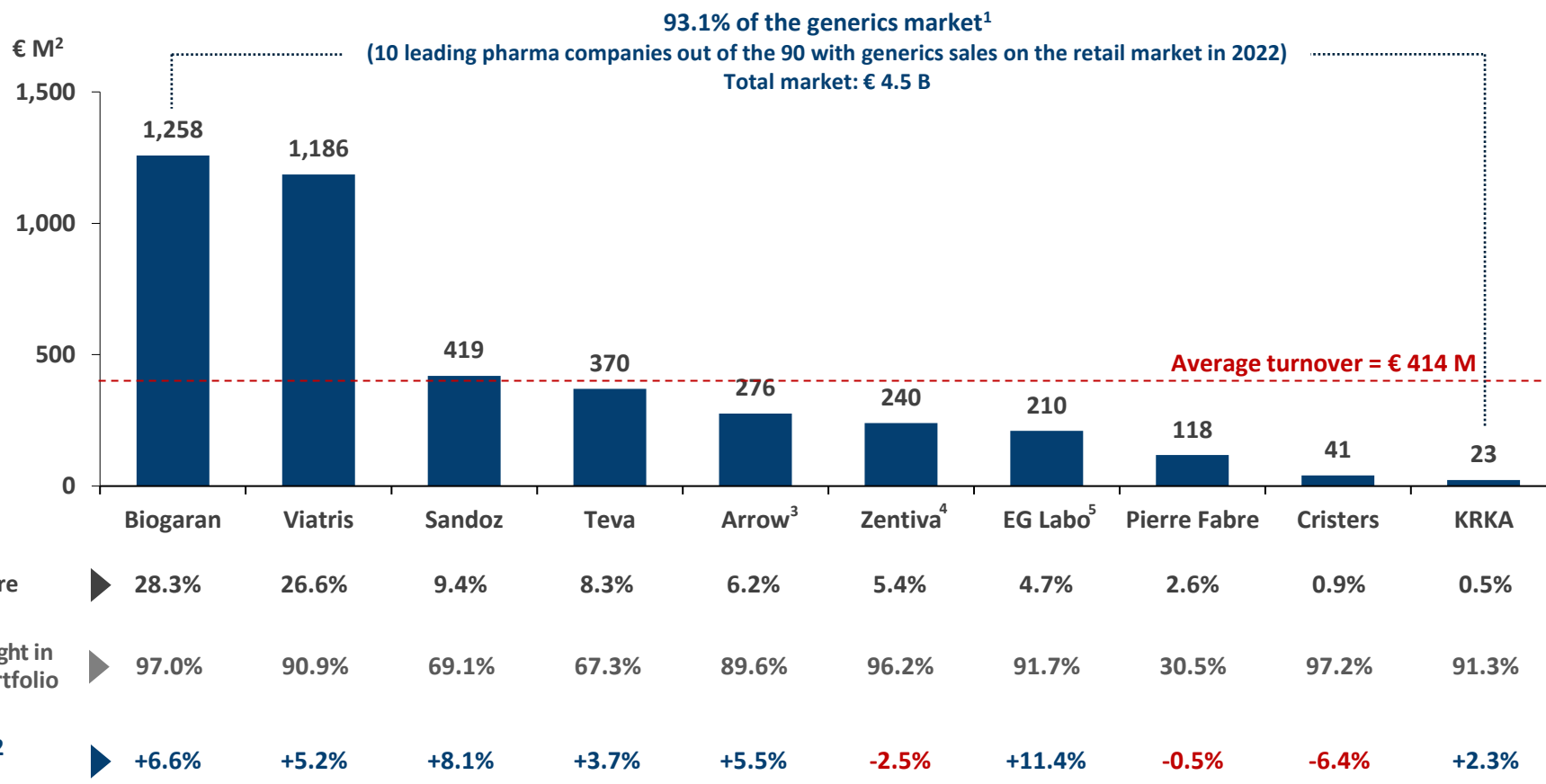
Sources: GEMME – GERS dashboards –
 Smart Pharma Consulting estimates

¹ Estimates based on the ex-factory prices which correspond approximately to what is reimbursed by the National Health Insurance Fund on reimbursed drugs (i.e., ~60% of the public price including 2.1% VAT) – ² In constant ex-factory price before taxes

In 2022, Biogaran and Viatris generated more than € 2.4 B sales and represented together ~55% of the French retail generic market in value

Top 10 generics companies on the retail market – In value (2022)

Gross price



Sources: GERS – Smart Pharma Consulting analyses

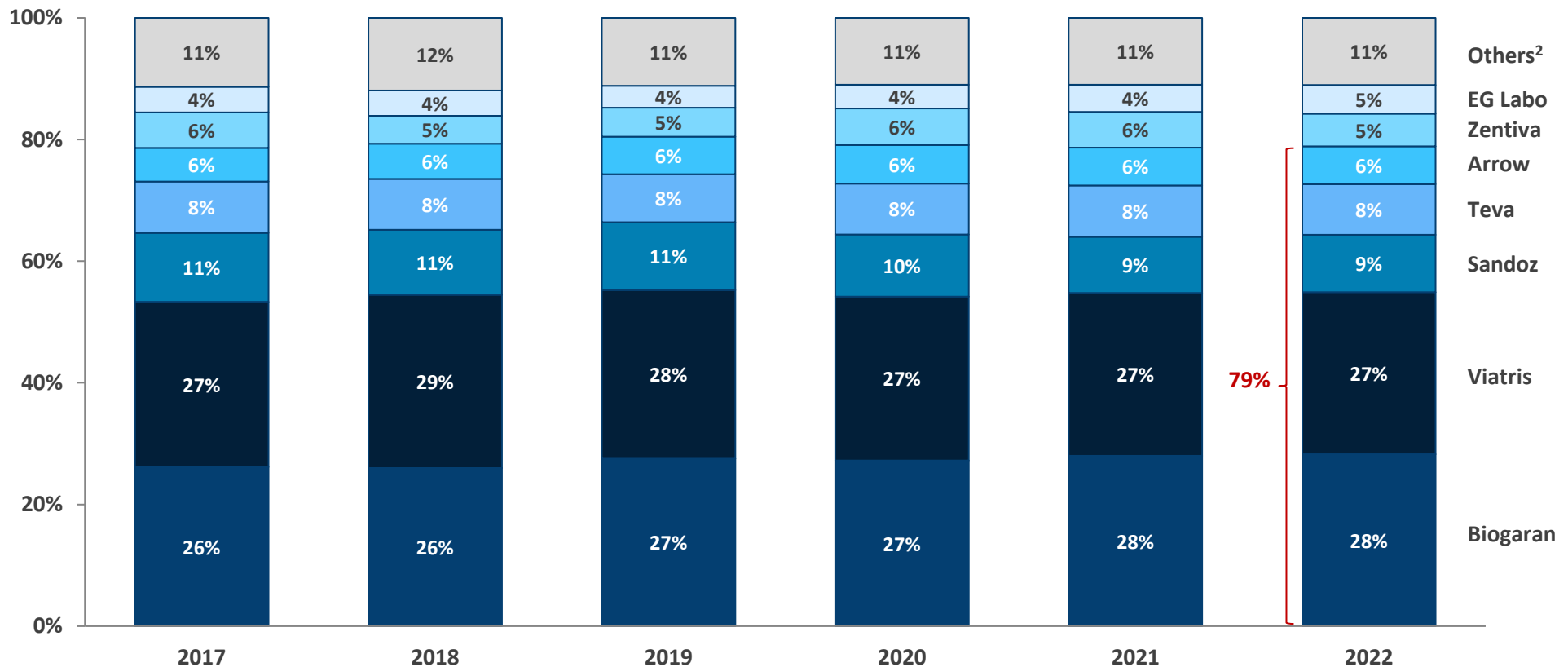
¹ Reimbursable and non-reimbursable, listed in the ANSM generics Directory, including quasi generics – ² Ex-factory price, before taxes and rebates – ³ Part of Aurobindo, since its acquisition of Actavis in 2014 – ⁴ Acquired by Advent International on September 30th, 2018 – ⁵ Subsidiary of Stada which was acquired by Bain Capital and Cinven in August 2017

The French generics market is concentrated with 79% of the sales captured by the top 5 players, whose market shares have been relatively stable since 2017

Market share of generics companies in the retail market (2017 – 2022)

Gross price

Generics market share in value¹



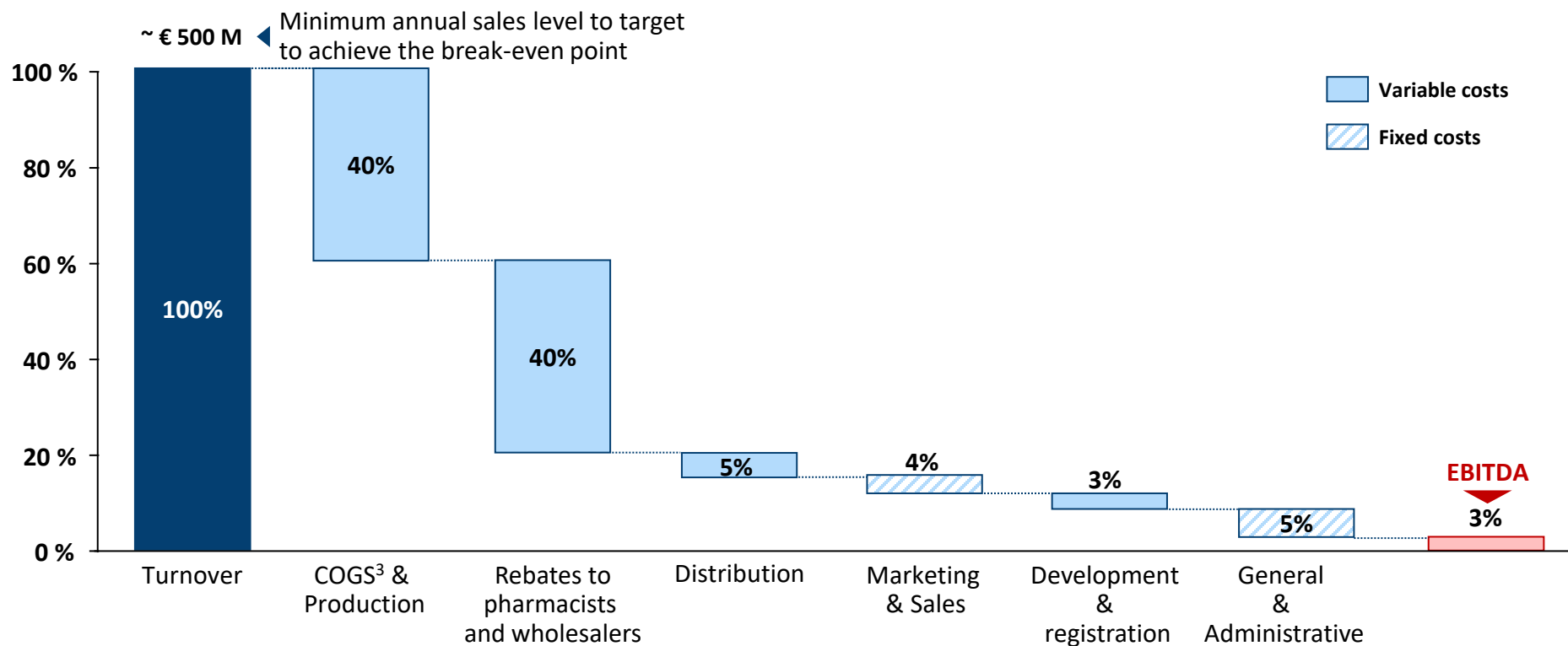
Sources: GERS – Smart Pharma Consulting analyses

¹ Ex-factory price, before taxes and rebates – ² Mostly Pierre Fabre, Pfizer and Cristers

The average turnover to generate operating profitability (EBITDA^{1,2}) is estimated at ~ € 500 M for generics companies operating in the retail market

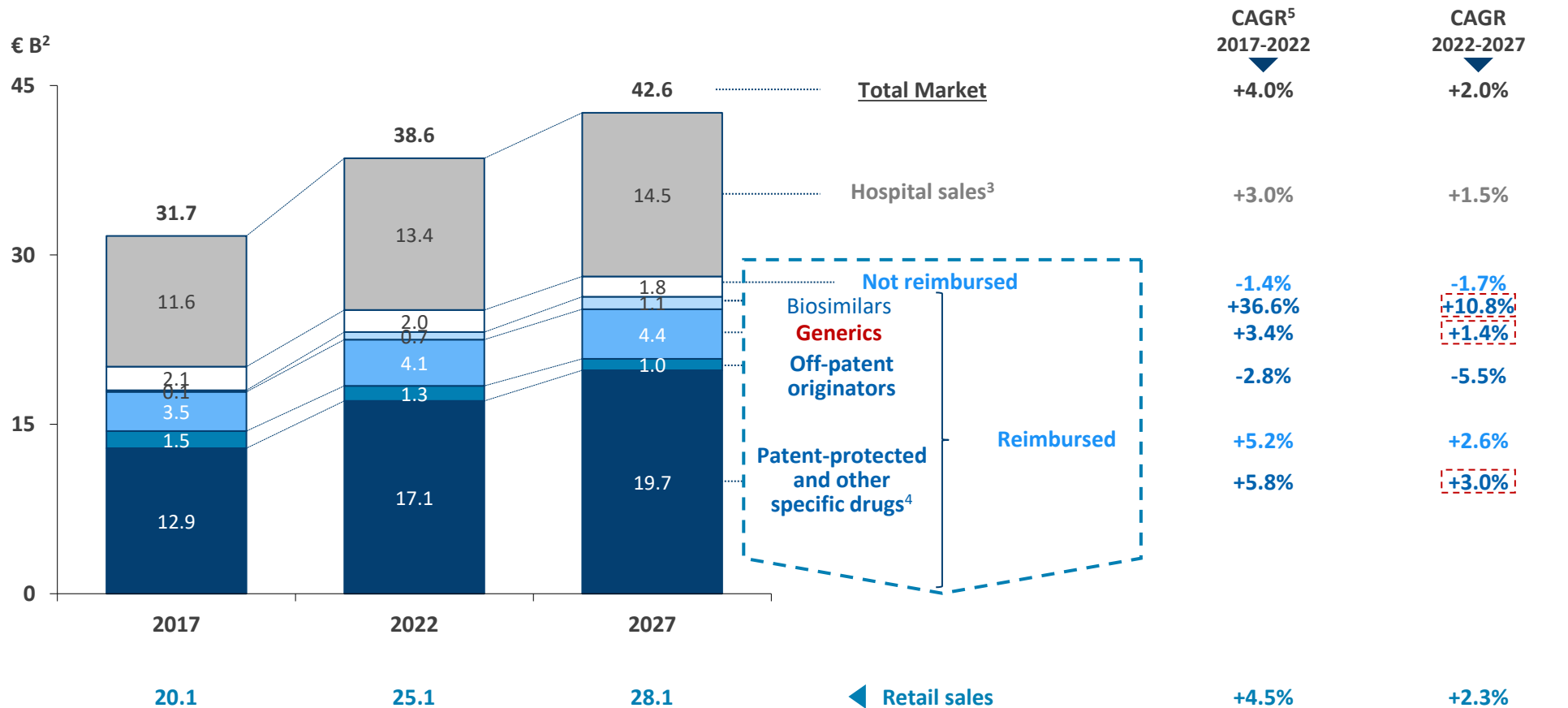
Average estimated cost structure of generics companies in the retail market

% of total sales



The retail generics market evolution over the 2022 – 2027 period – expressed in gross price – will mainly result from the patent expiry of originators and the price cuts imposed by the CEPS¹

Drugs sales forecast by segment (2017 – 2022 – 2027)

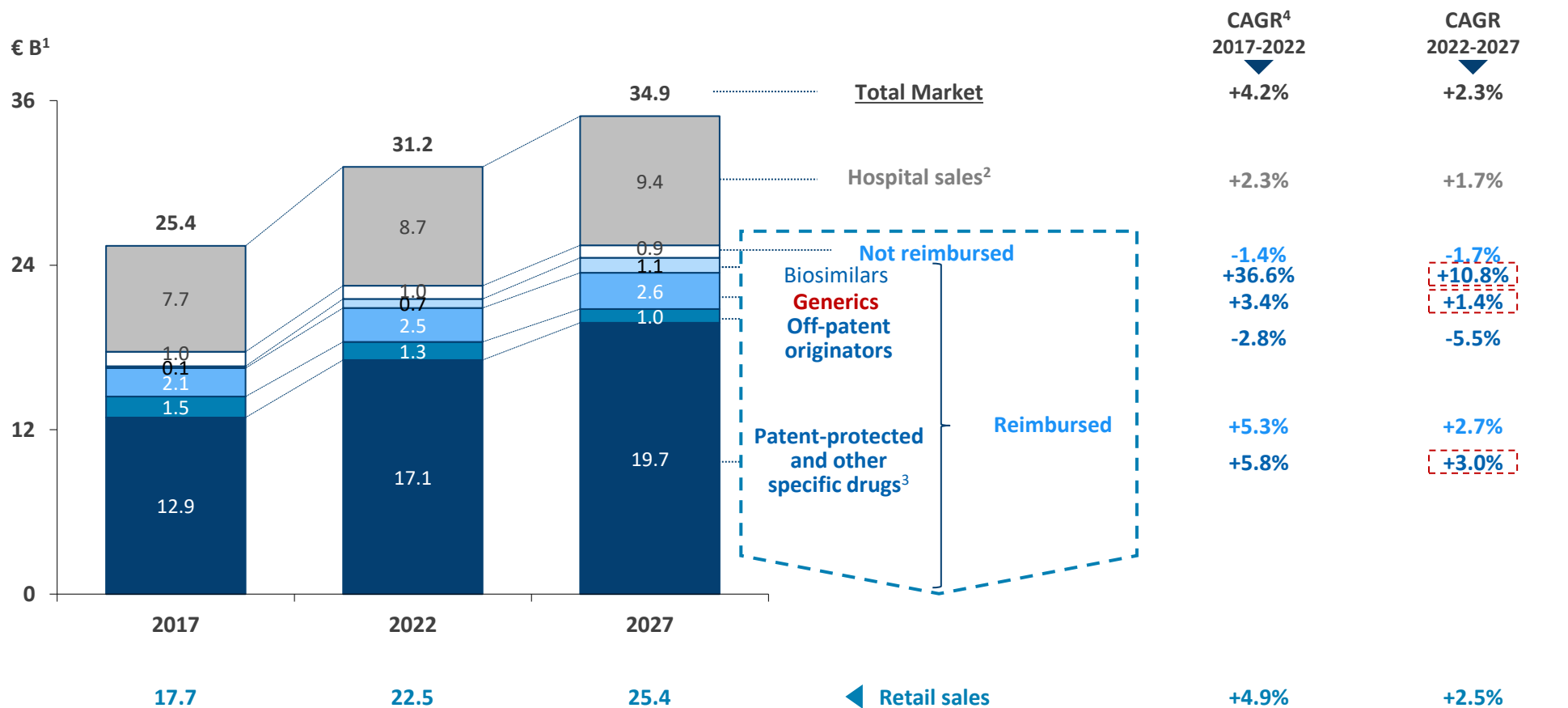


Sources: GERS dashboards –
 Smart Pharma Consulting estimates

¹ Drug pricing committee – ² Constant ex-factory prices, before rebates and taxes – ³ Including hospital sales of biosimilars, products invoiced on top of “T2A” and retroceded medicines – ⁴ Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.) – ⁵ Compound annual growth rate

It is estimated that in 2027, the retail generics market value expressed in net sales will account for 59% of the one in gross sales, considering the average discounts levels granted to pharmacists

Drugs sales forecast by segment (2017 – 2022 – 2027)



Sources: GERS dashboards –
 Smart Pharma Consulting estimates

¹ Constant ex-factory prices, before rebates and taxes – ² Including hospital sales of biosimilars, products invoiced on top of “T2A” and retroceded medicines
³ Sales of drugs whose patents have not expired and of other specific products (calcium, sodium, potassium, paracetamol, etc.) – ⁴ Compound annual growth rate

French health authorities will keep on supporting the development of the retail generics for economic reasons, and the market leaders will be in a better position to seize this opportunity

Key Takeaways

- The French retail generics market is expected to grow at +1.4% p.a. over the 2022 – 2027 period

- The government will keep on favoring the development of generics to contain the growth of reimbursed drug cost

- The market share of the two leaders (Biogaran & Viatris) should further increase from 55% to 60%¹

- The average discount level granted by generics companies to pharmacists (~40%) should not increase by 2027



- Product portfolio breadth and commercial offer are key determinants to be listed by VTOs² retail pharmacists adhere to

- Generics companies having the highest market share exhibit the highest level of profitability

- The profitability generated by retail generics should be maintained, or even slightly improve for the leading players

- The market growth will be strongly driven by the number and the importance of original brands which will lose their market exclusivity by 2027 and the price cuts imposed by health authorities through the CEPS³

Consulting firm dedicated to the pharmaceutical sector operating
in the complementary domains of strategy, management and organization

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- The Market Insights Series has in common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each issue is designed to be read in 15 to 20 minutes and not to exceed 24 pages

The French Retail Generics Market *Situation Analysis & 2027 Perspectives*

This paper analyzes the current market segment situation and estimates its perspectives of evolution

Thus, the following topics are covered:

- Regulatory framework
- Key stakeholders' analysis (health authorities / payers – retail pharmacists – competitors)
- Market drivers and limiters
- Review of sales in gross and net value (2017 – 2022 – 2027)
- Estimated profitability generated on the retail generics market

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching activities in advanced masters (ESSEC B-school, Paris Faculty of Pharmacy)
 - Training activities for pharma executives
 - The publication of articles, booklets, books and expert reports
- Our publications can be downloaded from our [website](#):
 - 41 articles
 - 78 position papers covering the following topics:
 1. Market Insights
 2. Strategy
 3. Market Access
 4. Medical Affairs
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny