



Healthcare Costs Regulation in France

Market Insights Series

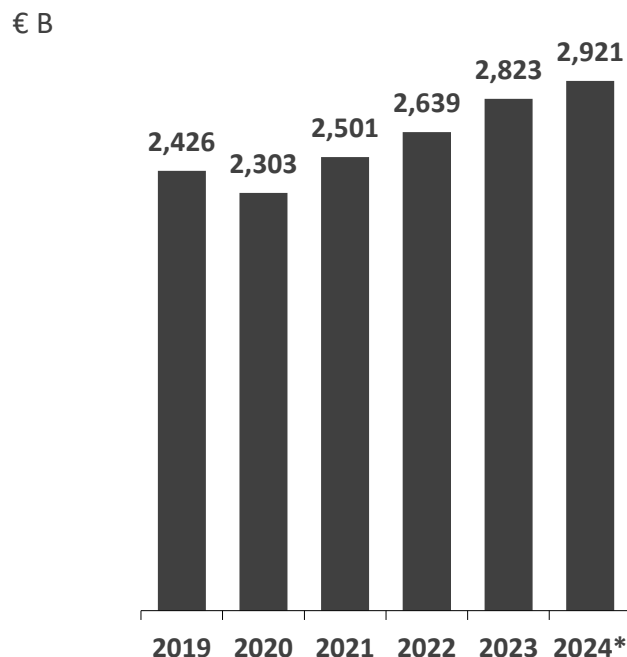
*Better Insights...
... for Better Anticipation*

November 2024

With a 2024 public deficit expected to amount to 6.1% of GDP and a public debt of 112.9% of GDP, France is far from the stability objectives defined at EU level (3% and 60%, respectively)

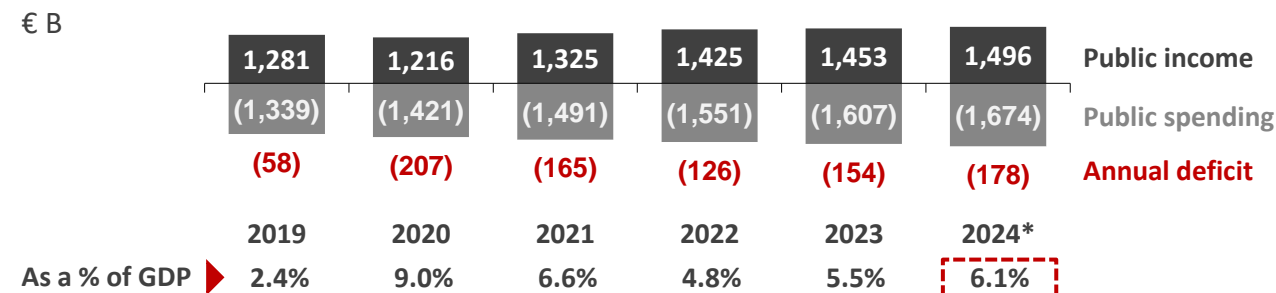
Key macroeconomic indicators (2019 – 2024)

GDP

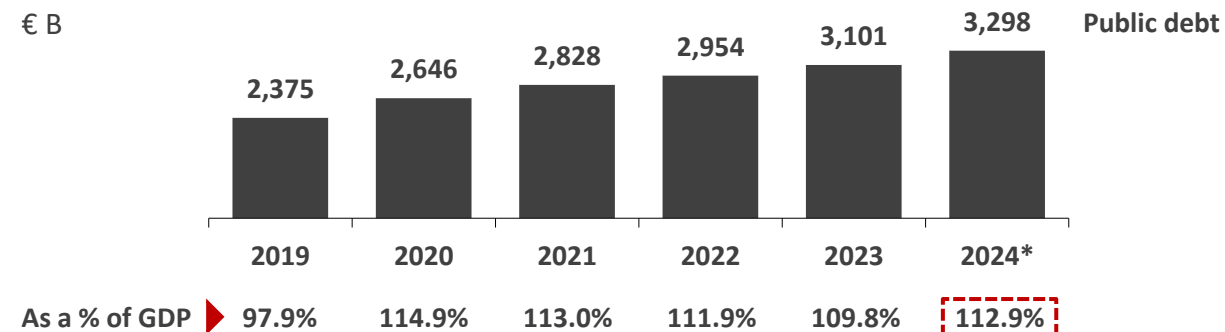


Real GDP growth¹ ▶ 1.5% (7.9%) 6.9% 2.6% 0.9% 1.1%

Public annual deficit



Public debt



* Estimates, based on the latest figures published by the Ministry of Economy

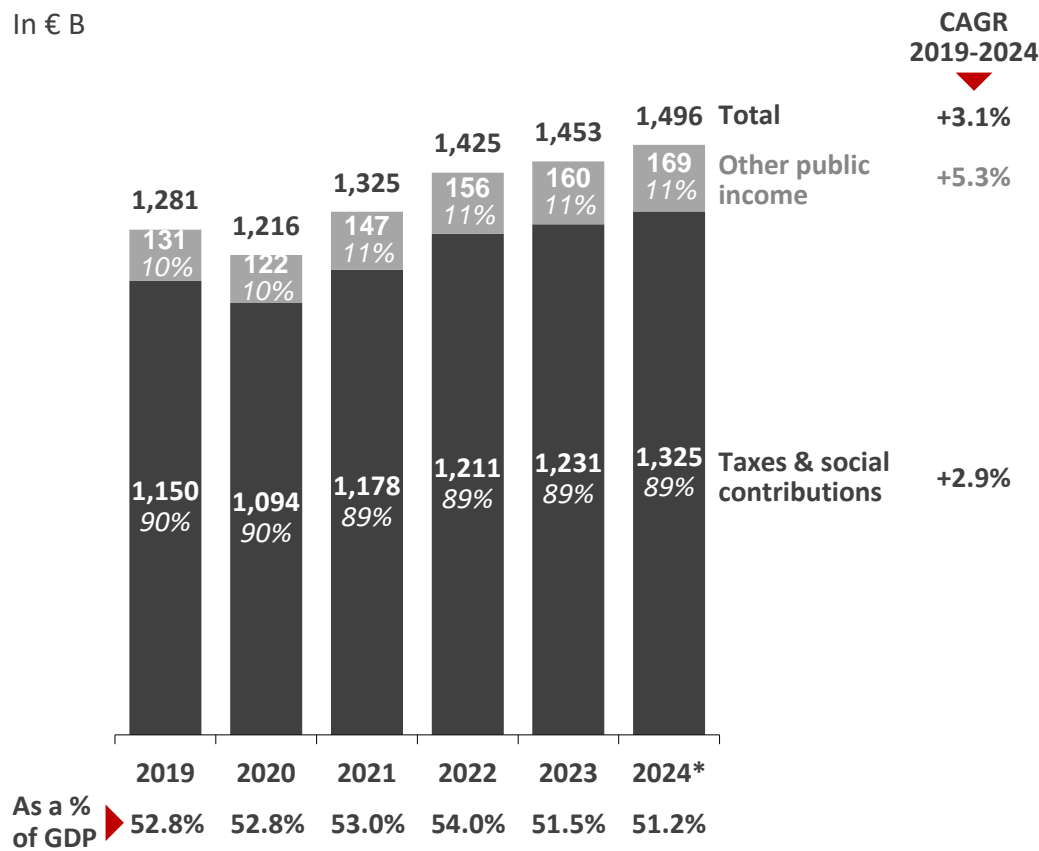
Sources: INSEE (November 2024) – HCFPS² opinion on the PLFSS³ 2025 (October 2024) – PLFG⁴ 2024 (November 2024) – PSMT⁵ 2025-2029 (October 2024) – Stability and Growth Pact (1997) – Maastricht Treaty (1992) – Smart Pharma Consulting analyses

¹ GDP growth rate adjusted for inflation – ² Haut Conseil des Finances Publiques: High Council of Public Finances – ³ Projet de Loi de Financement de la Sécurité Sociale: Social Security Financing Act Project – ⁴ Projet de Loi de Finance de Fin de Gestion: Project of Financial Law – ⁵ Plan budgétaire et Structurel à Moyen Terme: Medium Term Budgetary and Structural Plan

Taxes and social contributions account for 89% of public income, which highly depends on GDP growth that the government estimates at less than +1.5% p.a. over the 2025 – 2028 period

Public income (2019 – 2024)

In € B



- Taxes and social contributions account for ~89% of total public income:
 - Social contributions: ~32%
 - Taxes on production (incl. VAT) & imports: ~31%
 - Taxes on revenues (incl. income taxes) & wealth: ~25%
 - Taxes on the capital: ~1%
- Other public incomes (~11%) include:
 - Production revenues¹: ~7%
 - Property incomes²: ~1%
 - Other public incomes: ~3%
- Thus, **public income** highly **depends on economic growth**
- With a real **GDP growth** estimated to range from **+1.1%** to **+1.5%** from **2025** to **2028** (as assumed by the Ministry of Economy in its 2025-2029 PSMT⁶), public income should not increase significantly, unless the government takes new compulsory levy measures

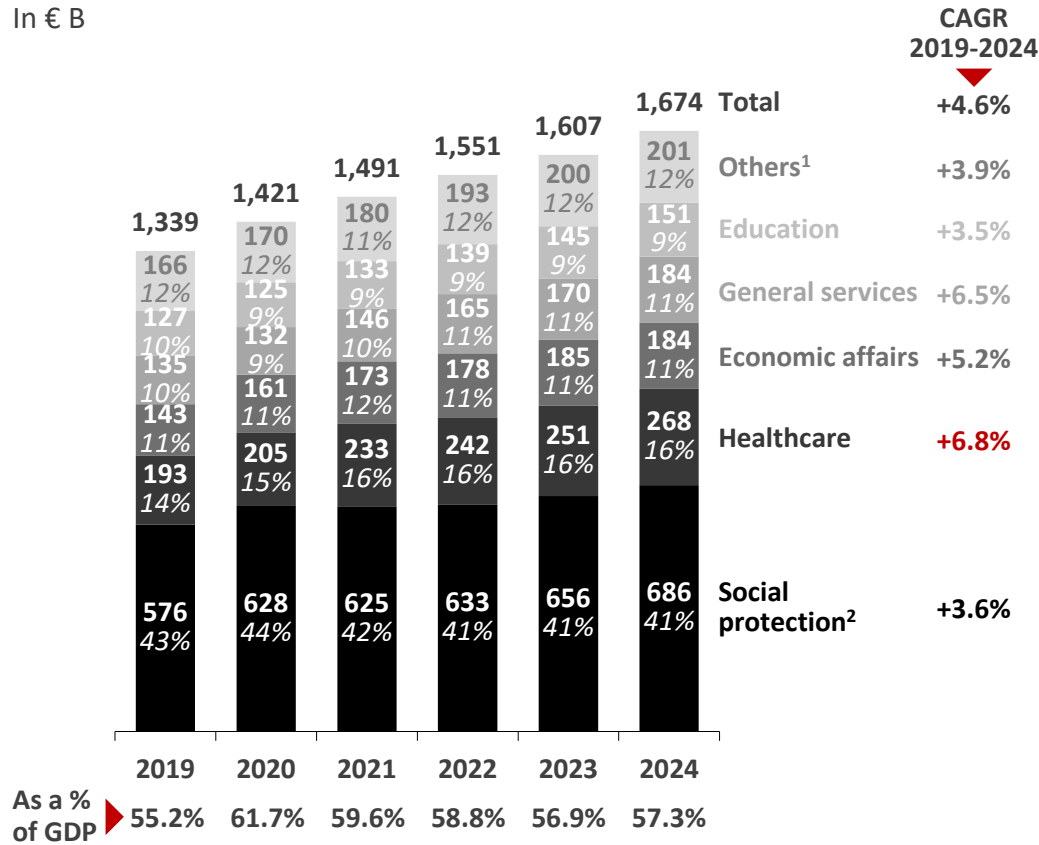
* Estimates, based on the latest figures published by the Ministry of Economy

Sources: INSEE (November 2024) – HCFPS³ opinion on the PLFSS⁴ 2025 (October 2024) – PLFG⁵ 2024 (November 2024) – PSMT⁶ 2025-2029 Finances Publiques: High Council of Public Finances –⁴ Projet de Loi de Financement de la Sécurité Sociale: Social Security Financing Act Project –⁵ Projet de Loi de Finance de Fin de Gestion: Project of Financial Law –⁶ Plan budgétaire et Structurel à Moyen Terme: Medium Term Budgetary and Structural Plan

Although the government and the public payer try to contain the rise of healthcare expenditures, their weight keeps on growing in total public spending

Public spending (2019 – 2024)

In € B



CAGR 2019-2024



+4.6%

- In 2024, public spending in healthcare should reach € 268 B
- It should account for 16% of the total public spending (+2 pts vs. 2019 due to a +6.8% CAGR, higher than the +4.6% CAGR for total public spending and the +3.1% CAGR for total public income)
- It is the 2nd largest public spending item, after social protection
- It is distributed as follows:
 - Hospital services (41%)
 - Ambulatory services (35%)
 - Drugs and medical devices (16%)
 - Public health services (5%)
 - Other items such as public research (3%)
- Drugs is the 3rd largest source of healthcare costs and the easiest on which to apply cost-containment measures as:
 - It is politically better accepted by citizens than any restriction on the other healthcare segments
 - It is technically and practically easy to implement considering the high bargaining power of the government and the public payer vs. pharma companies

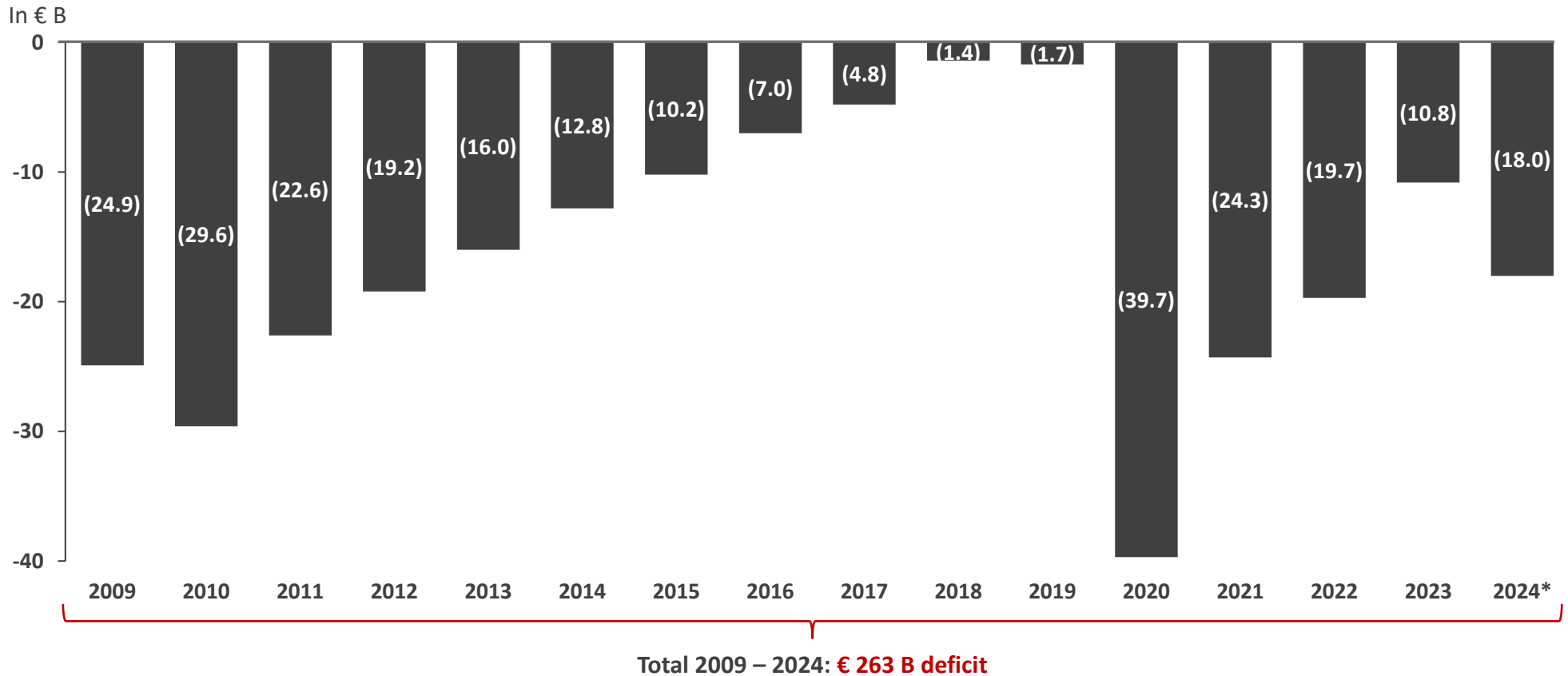
* Estimates, based on the latest figures published by the Ministry of Economy

Sources: INSEE (November 2024) – HCFPs opinion on the PLFSS 2025 (October 2024) – Smart Pharma Consulting analyses

¹ Incl. defense (3%), public order and safety (3%), leisure, culture and worship (2%), housing and collective facilities (2%) and environmental protection (2%) – ² Incl. old-age solidarity fund (22%), work stoppages due to illness or disability (5%), family and children (4%), unemployment (3%), social exclusion (2%) and others (5%)

The National Health Insurance Fund cumulated a € 263 B deficit since 2009, of which ~€ 40 B in 2020, resulting from the Covid-19 crisis

National Health Insurance Fund deficit – General regime¹ evolution (2009 – 2024)



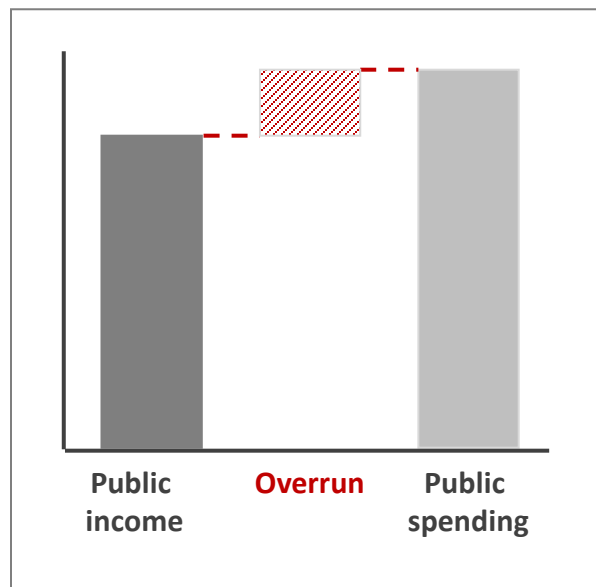
* As estimated in the PLFSS 2025

Sources: Court of Auditors report (October 2024) – PLFSS 2025 (October 2024) – Smart Pharma Consulting analyses

¹ Including old-age solidarity fund (FSV: “Fonds de solidarité vieillesse”)

The government can activate four levers to regulate the cost of the drugs reimbursed by the National Health Insurance Fund

Levers to regulate drug public spending



1

Drugs price & reimbursement

- Price is set by the CEPS at drug launch and then revised down, along the product life cycle (before and after patent expiry)
- The reimbursement rate is set by the MoH, on the recommendation of the Transparency Committee of the HAS (National Authority for Health)¹ and can be modified over time

2

Drugs rebates to the National Health Insurance Fund

- Rebates (i.e., paybacks) are set by the CEPS² according to various schemes
- These rebates apply mainly to products having the most impact³ on drugs cost increase from one year to another
- These rebates do not apply to generics and biosimilars

3

Clawback

- When the net sales of pharma companies exceed the “M amount” (e.g., € 26.4 B for the year 2024) voted by the Parliament for the year to come, they must repay an unpredictable part of the overrun, based on a changing and unclear calculation method

4

Medical control of the healthcare expenses

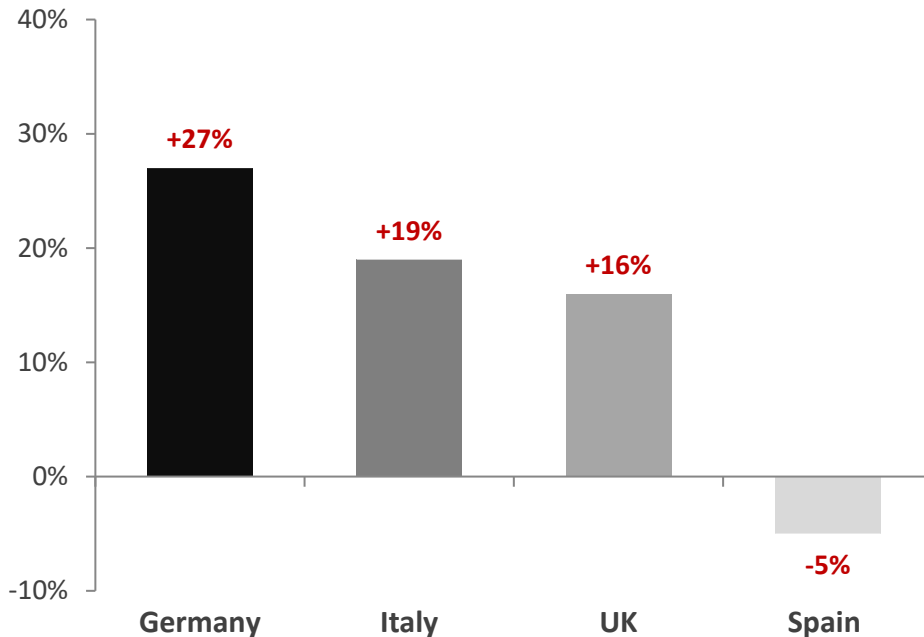
- Actions implemented by the National Health Insurance Fund to improve the appropriateness of care and reduce the unnecessary consumption of drugs

When compared to the four largest pharma markets in Europe, the average regulated prices of drugs in France are the lowest, irrespective of whether generics are present or not

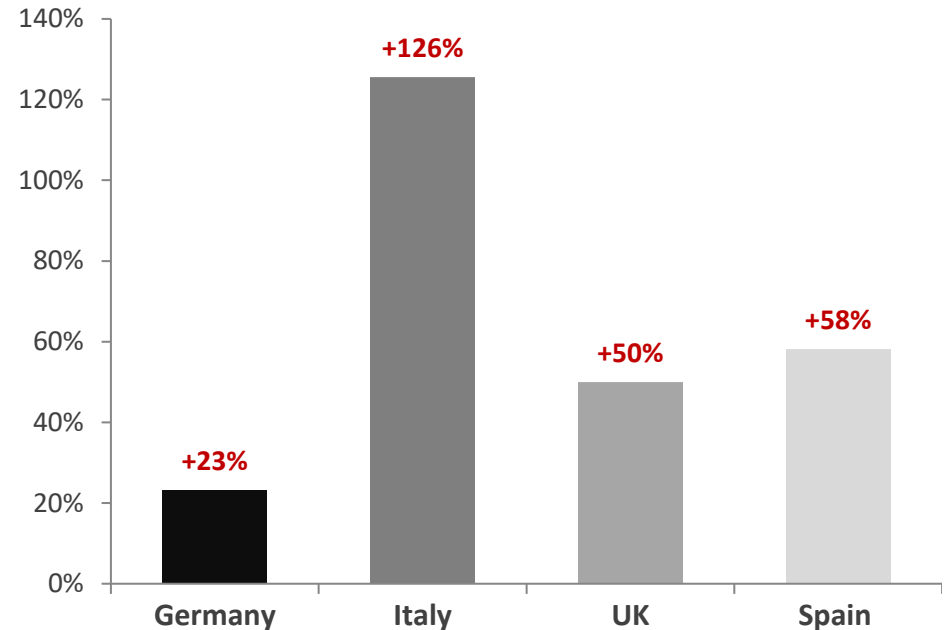


Drugs price & reimbursement: International comparisons (2023)

Price differences of selected countries vs. France
Without generic direct competition



Price differences of selected countries vs. France
With generic direct competition



Percentage in relation with the French average regulated price

Sources: International price comparisons 2023, TLV & IQVIA (January 2024) – Smart Pharma Consulting analyses

In 2022, the total net rebates due by pharma companies to the CEPS¹ reached € 7.5 B (incl. € 1.2 B clawback rebates)



Drugs rebates to the National Health Insurance Fund & Clawback (2022)

3 types of rebates due by pharma companies to the CEPS

	Conventional rebates specific to certain products	Early Access Program (EAP) rebates	Clawback (also called "Safeguard clause" or "M contribution")
Description	<p>Clauses agreed between CEPS and pharma companies for 349 specific products</p> <ul style="list-style-type: none"> ▪ "First-pack" clawbacks ▪ Volume clauses ▪ Capping clauses ▪ Daily dosage clauses ▪ Performance clauses 	<p>Rebates due when the reference price decided by the CEPS is lower than the price invoiced during its EAP period</p> <ul style="list-style-type: none"> ▪ Until July 2021, the maximum price per patient per year was € 10,000 for annual sales above € 30 M ▪ Since then, the cap has been removed but specific rebates have been established based notably on product annual sales 	<ul style="list-style-type: none"> ▪ Rebates depending on whether an amount of drugs expenses (the "M amount") is exceeded at year-end ▪ The M amount was set as follows: <ul style="list-style-type: none"> – € 24.0 B in 2021 (+1.2% vs. 2020) – € 24.5 B in 2022 (+2.1% vs. 2021) – € 24.9 B in 2023 (+1.6% vs. 2022) – € 26.4 B in 2024 (+6.0% vs. 2023)
Rebates in 2022 (gross amount)	€ 5.7 B	€ 0.8 B	€ 1.2 B

$\Sigma = € 7.7 B$ gross amount, representing a net amount of € 7.5 B²

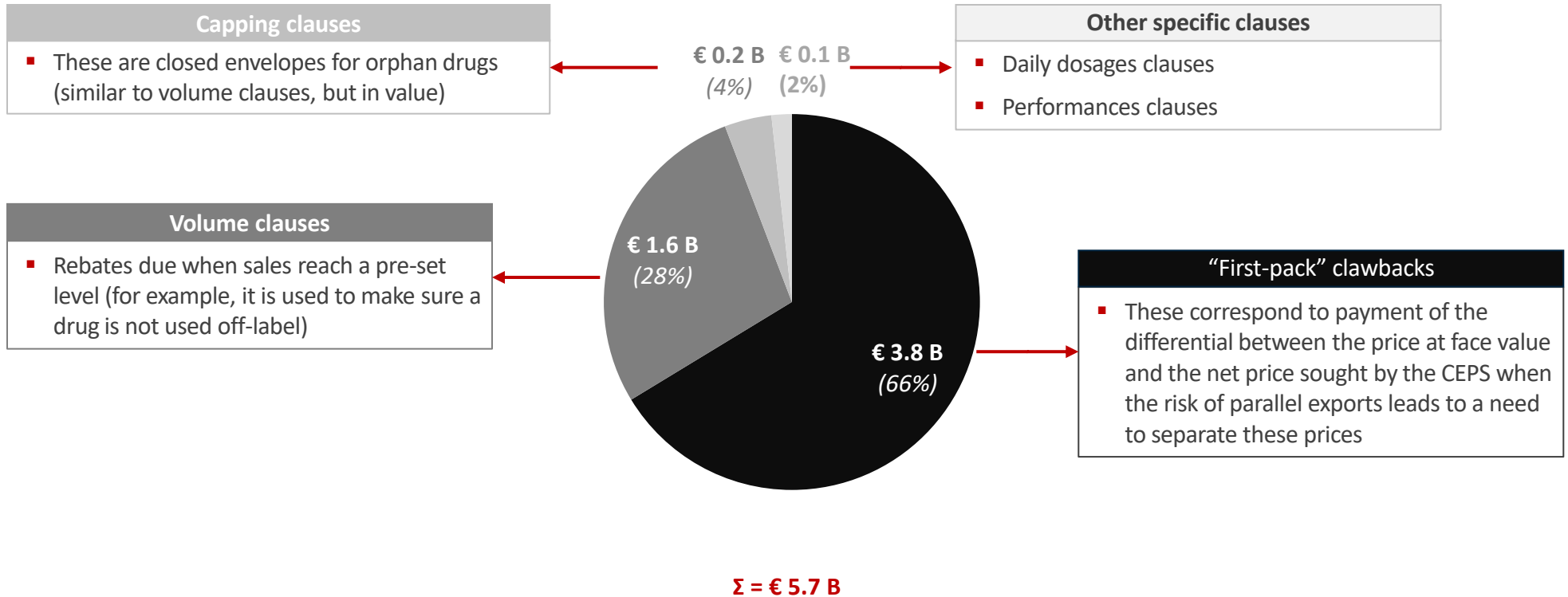
Sources: CEPS annual report (January 2024) – LFSS 2024 (December 2023) – Smart Pharma Consulting analyses

¹ Comité Economique des Produits de Santé; Drug Pricing Committee –
² After deducting € 201 M of credit notes on rebates

Specific clauses may be added to conventions between the CEPS¹ and pharma companies, leading to potential rebates (i.e., paybacks) on certain products depending on various factors



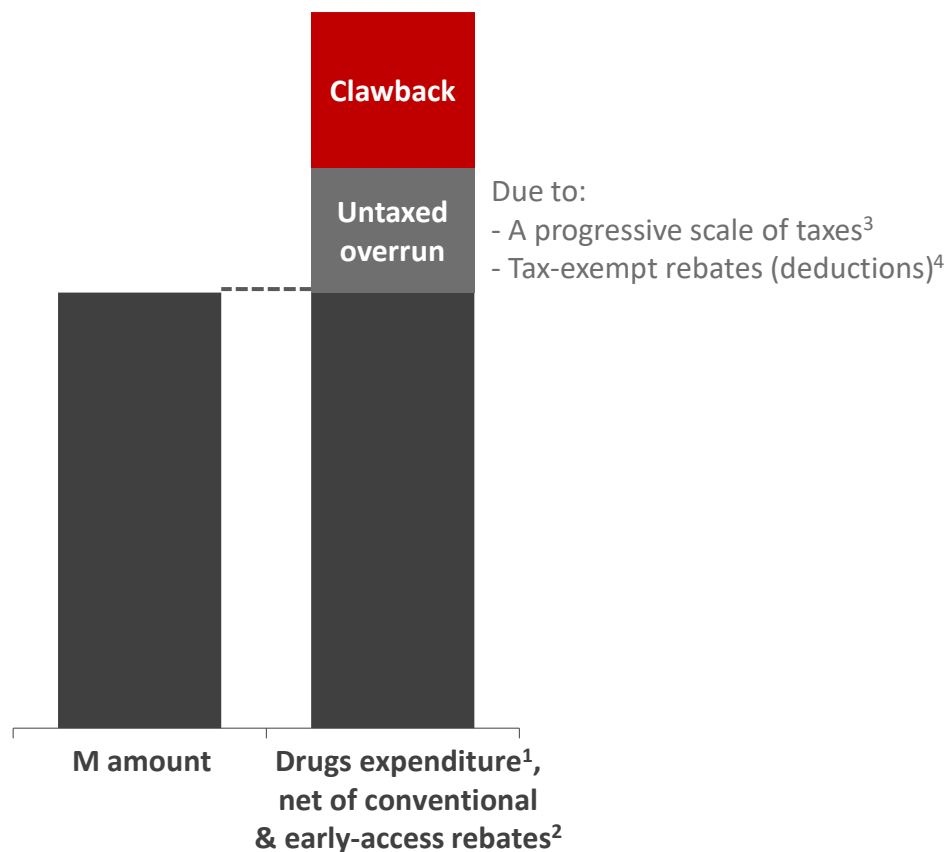
Conventional rebates specific to certain products (2022)



The clawback is a provision created in 1999 aiming to regulate the health expenditure related to drugs by taxing the pharmaceutical companies

3

Clawback – Definition



- The clawback (also known as “**safeguard clause**” or “**M contribution**”) has been created by the 1999 LFSS (Social Security Financing Act)
- It is a financial regulation of the **drugs** market
- The objective is to **limit National Health Insurance Fund expenditure** by imposing a greater financial burden on the market players **who contribute most to this expenditure** and to its **growth**
- This mechanism is **triggered** when **drugs expenditure** exceeds a **threshold** (the “**M amount**”)
- The value of the “**M amount**” is set each year in relation to the national health insurance expenditure target (ONDAM), by the parliament and voted under the LFSS
- The clawback is **regularly criticized** and has **evolved considerably** through the successive LFSS
- For **2024**, the “**M amount**” was set at € 26.4 B (+6.0% vs. 2023)

Sources: CEPS annual report (January 2024) – LFSS 2024 (December 2023) – Smart Pharma Consulting analyses

¹ Incl. retail sales and hospital sales for on-top of T2A and retrocession drugs – ² Money reimbursed to the National Health Insurance Fund, corresponding to the gap between the official list price and the net price negotiated with the CEPS – ³ 50% on the portion of the overrun between 0 and 0.5 point, 60% on the portion of the overrun between 0.5 and 1 point and 70% on the portion of the overrun exceeding 1 point – ⁴ From 5% to 20% for companies under agreement, depending on pharma companies contribution to savings through net price cuts

Generics were exempted from the clawback until 2019, date from which they were included in the mechanism

Clawback – Principles (1/2)

3

	1999/2000	2001-2005	2005-2009	2010	2011-2014	2015-2016	2017	2018	2019-2021	2022	2023
Companies scope	<ul style="list-style-type: none"> Not under agreement with the CEPS 					<ul style="list-style-type: none"> All companies Those that have signed an agreement with the CEPS pay a contribution equivalent to the clause minus an abatement 					
Rebates (deductions) on the clawback						<ul style="list-style-type: none"> 20% rebate for companies under agreement 			<ul style="list-style-type: none"> 5% to 20% rebate for companies under agreement 		
Drugs scope											
Retail original drugs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Retrocession (list 5126-4)			✓	✓	✓	✓	✓	✓	✓	✓	✓
On top of T2A				✓	✓	✓	✓	✓	✓	✓	✓
Early access programs and list 162-16-5						✓	✓	✓	✓	✓	✓
Very Early Access											✓
Import or distribution specialties										✓	✓
Generics									✓	✓	✓
Orphan drugs					Sales>€30M	Sales>€30M	Sales>€30M	Sales>€30M	✓	✓	✓
Growing innovative drugs											✓
Drugs bought by SPF ¹											✓

Sources: Legifrance – Smart Pharma Consulting analyses

¹ Santé Publique France: Public agency with expertise in prevention, education and health promotion

Since 2023, the clawback is distributed amongst pharma companies based on both revenues and growth (70% and 30% of the contribution, respectively)

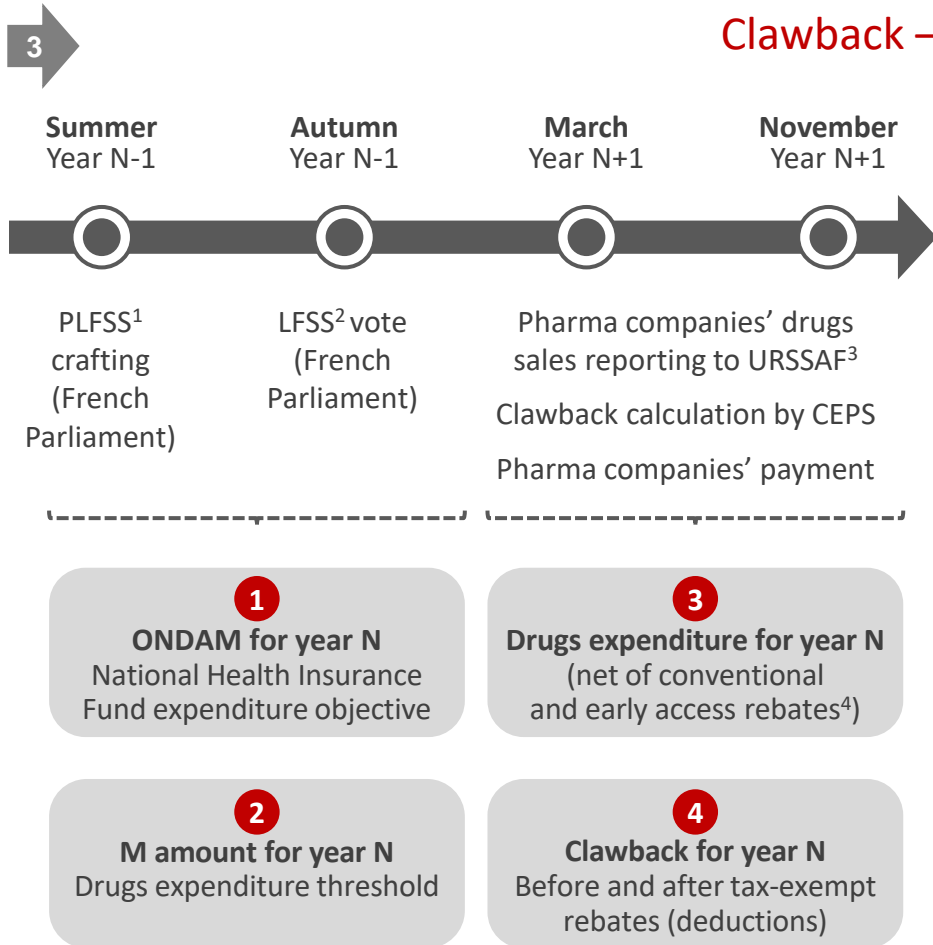
3 Clawback – Principles (2/2)

	1999/2000	2001-2005	2005-2009	2010	2011-2014	2015-2016	2017	2018	2019-2021	2022	2023
Revenues deduction						<ul style="list-style-type: none"> Conventional rebates (e.g., capping, pay for performance and/or price-volume agreements, early access rebates) 					
Authorized growth of total reimbursable rate	<ul style="list-style-type: none"> Rate of increase of the ONDAM but substituted from 2000, by a specific K rate¹ 	<ul style="list-style-type: none"> ONDAM progression rate but substituted by a specific and identical K rate for the 2 subgroups (retail and hospital markets) 				<ul style="list-style-type: none"> L rate¹ 	<ul style="list-style-type: none"> Lv rate (retail market) Lh rate (hospital market) 			<ul style="list-style-type: none"> M rate¹ (%) 	<ul style="list-style-type: none"> M amount (in €)
Tax rates	<ul style="list-style-type: none"> Between 0.15% and 3.3% of sales depending on the overrun 	<ul style="list-style-type: none"> 50% on the portion of the overrun between 0 and 0.5 point 60% on the portion of the overrun between 0.5 and 1 point 70% on the portion of the overrun exceeding 1 point 									
Method of distribution	<ul style="list-style-type: none"> 30% on the share of sales / overall sales 40% on the share of sales growth in relation to overall growth 30% on the share of promotional expenses in relation to overall promotional expenses 					<ul style="list-style-type: none"> 50% on the share of sales/overall sales 50% on the share of sales growth in relation to overall growth 		<ul style="list-style-type: none"> 100% on the sales 		<ul style="list-style-type: none"> 70% on the sales 30% on growth 	

Sources: Legifrance – Smart Pharma Consulting analyses

¹ Specific rate applicable on the total market

The clawback is a source of uncertainty for pharma companies operating in France, even if the LFSS 2023 stated that the calculation and the payment had to be completed on November N+1



- In recent years, the definitive amount of the clawback was not known until the last quarter of the following year, and even in January 2023 for the 2021 clawback
- The LFSS 2023 redefined the legal timetable, providing that all the process had to be completed on November N+1
- Therefore, the net drugs expenditure of the pharmaceutical industry from the previous year is unknown during the crafting of the PLFSS, which is regularly criticized by pharma companies and even by the Court of Auditors
- This situation leads to a strong unpredictability of the clawback, impairing French subsidiaries attractiveness:
 - Gaps between estimates and actual amounts of the clawback are difficult to understand for parent companies and auditors
 - Negative impact on budget management, with estimates changes that may lead some French affiliates to reopen their previous year financial accounts

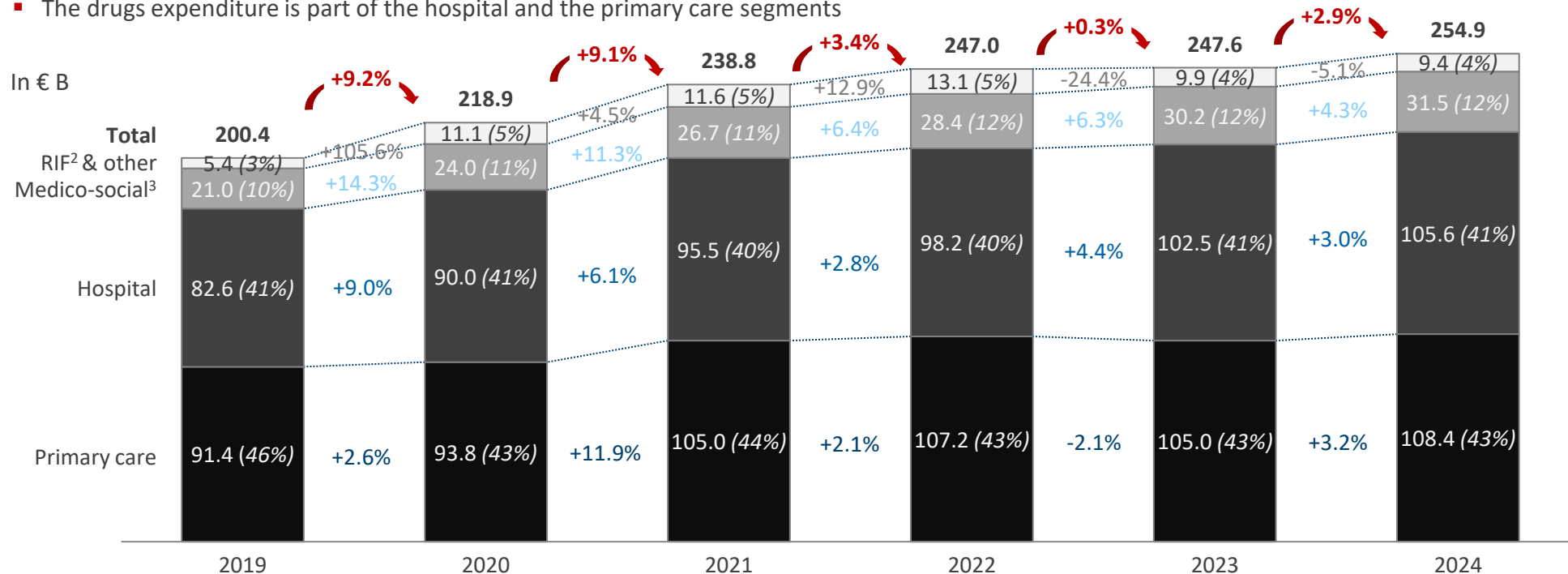
Sources: CEPS annual report (January 2024) – PLFSS & Médicament, Leem (September 2024) – LFSS 2023 (article 18) – Smart Pharma Consulting analyses

¹ Social Security Financing Act Project – ² Social Security Financing Act – ³ Previously called ACOSS – ⁴ Money reimbursed by pharma companies to the National Health Insurance Fund, based on a predefined agreement (e.g., amount corresponding to the difference between the official drug price list and the net price negotiated with the CEPS). These rebates apply to certain original drugs, but not to generic, nor to biosimilars

The 2024 ONDAM¹ fixed the annual growth of healthcare expenditure at +2.9% with a higher growth on Medico-social (+4.3%) than Hospital (+3.0%) and Primary care (+3.2%)

1 ONDAM evolution (2019 – 2024)

- The ONDAM is not a budget, but an objective of healthcare spending funded by the National Health Insurance Fund that should not be exceeded
- It is set every year by the Social Security Financing Act (LFSS) which is voted by the Parliament
- The ONDAM does not correspond to all the healthcare benefits considered in the national accounting
- The drugs expenditure is part of the hospital and the primary care segments

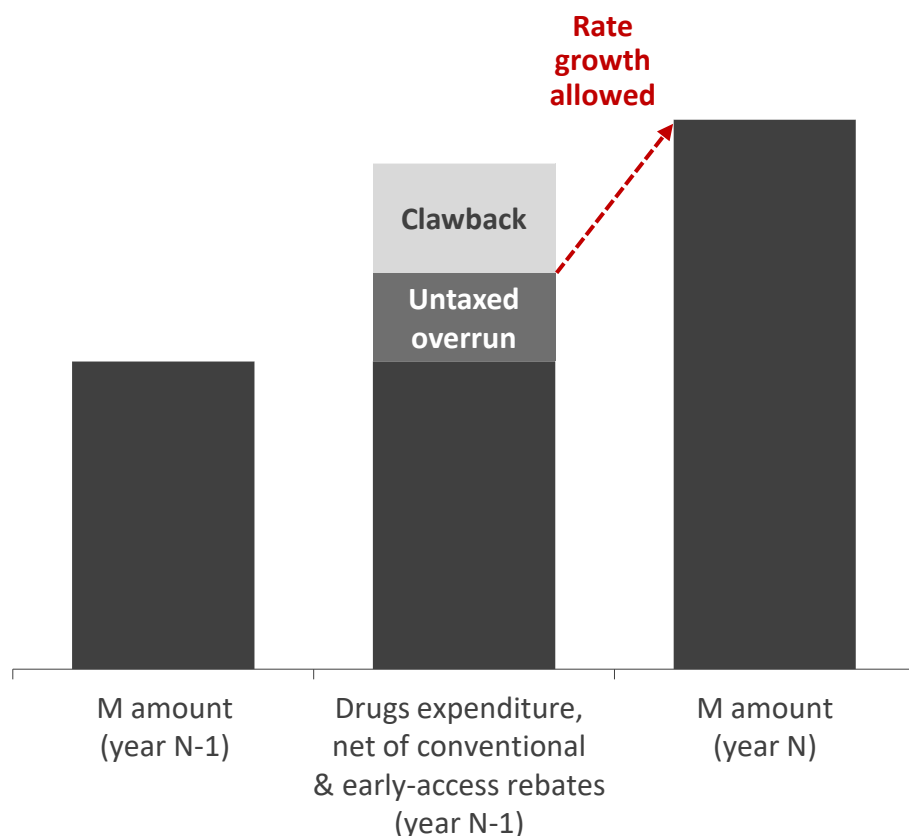


Sources: LFSS 2019 to 2024 – DREES (June 2023) – Smart Pharma Consulting analyses

¹ National objective for National Health Insurance Fund expenditure – ² Regional intervention fund – ³ Including contribution to old-age institutions and to institutions for disabled persons

The setting methodology of the M amount is less and less transparent, and may even give rise to retrospective adjustments as it was the case in the LFSS 2024 (for the 2023 M amount)

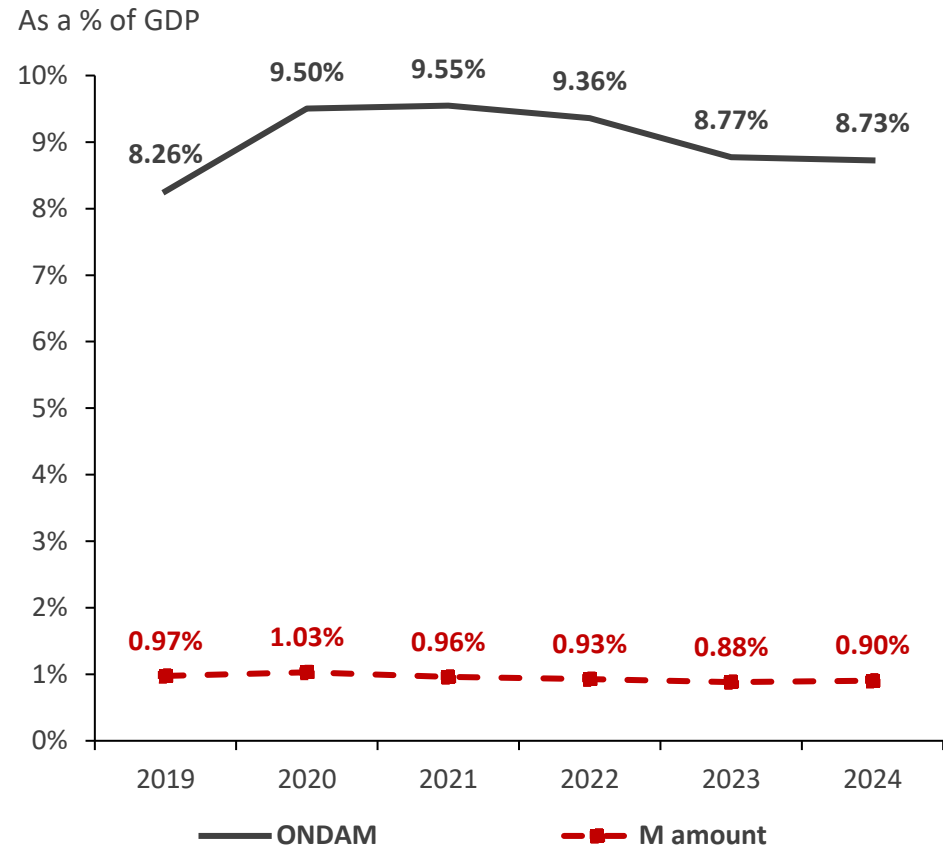
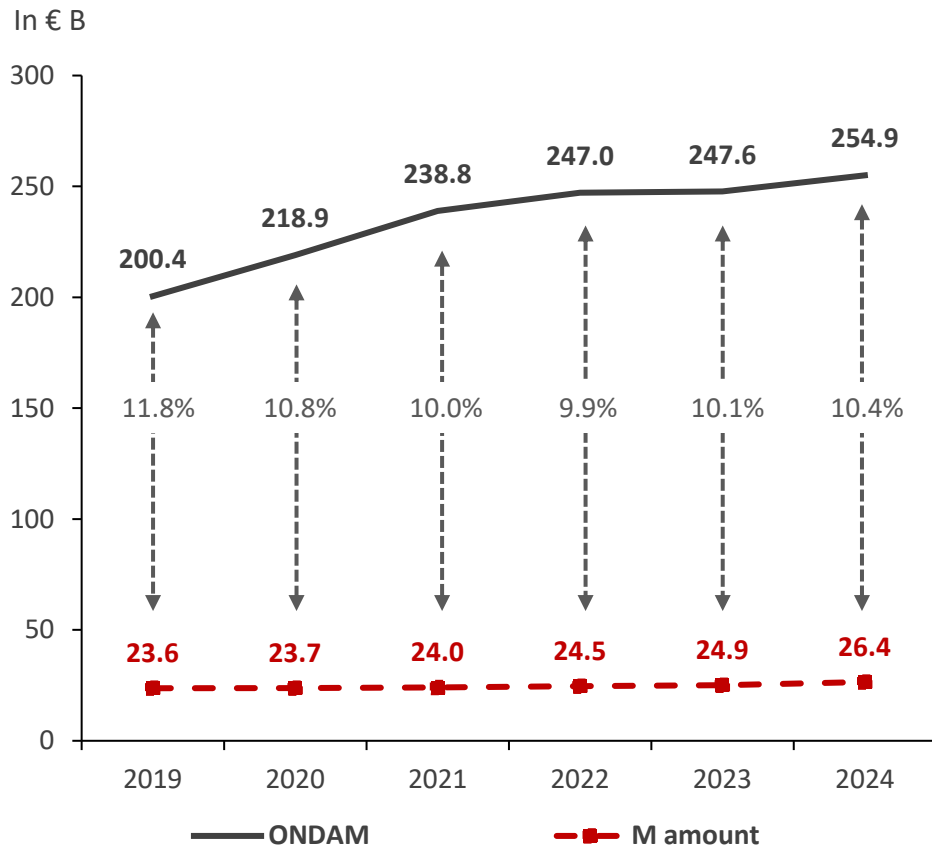
2 M Amount – Setting methodology



- Between 2015 and 2020, the methodology used to set the triggering threshold of the clawback was established by law
- If this description has no longer appeared in the law, the Administration used the same methodology in the years 2021 and 2022
- The rule applied to set the M amount was as follows:
(Net drugs expenditure N-1 – clawback N-1) x Growth rate
- This rebasing method allowed to link the evolution of the M amount with the pharmaceutical market evolution (based on the evolution of population needs)
- In 2023, the methodology used to set the M amount was not made public, with a M amount initially set at € 24.6 B (i.e., a +0.4% growth rate vs. 2022)
- The LFSS 2024 eventually revised the M amount for 2023 to € 24.9 B (+1.6% vs. 2022)

For 2024, the ONDAM¹ has been set at € 255 B (i.e., 8.7% of the GDP), and the M amount² at ~€ 26.4 B (~10.4% of the ONDAM)

2 M Amount – Evolution (2019 – 2024)



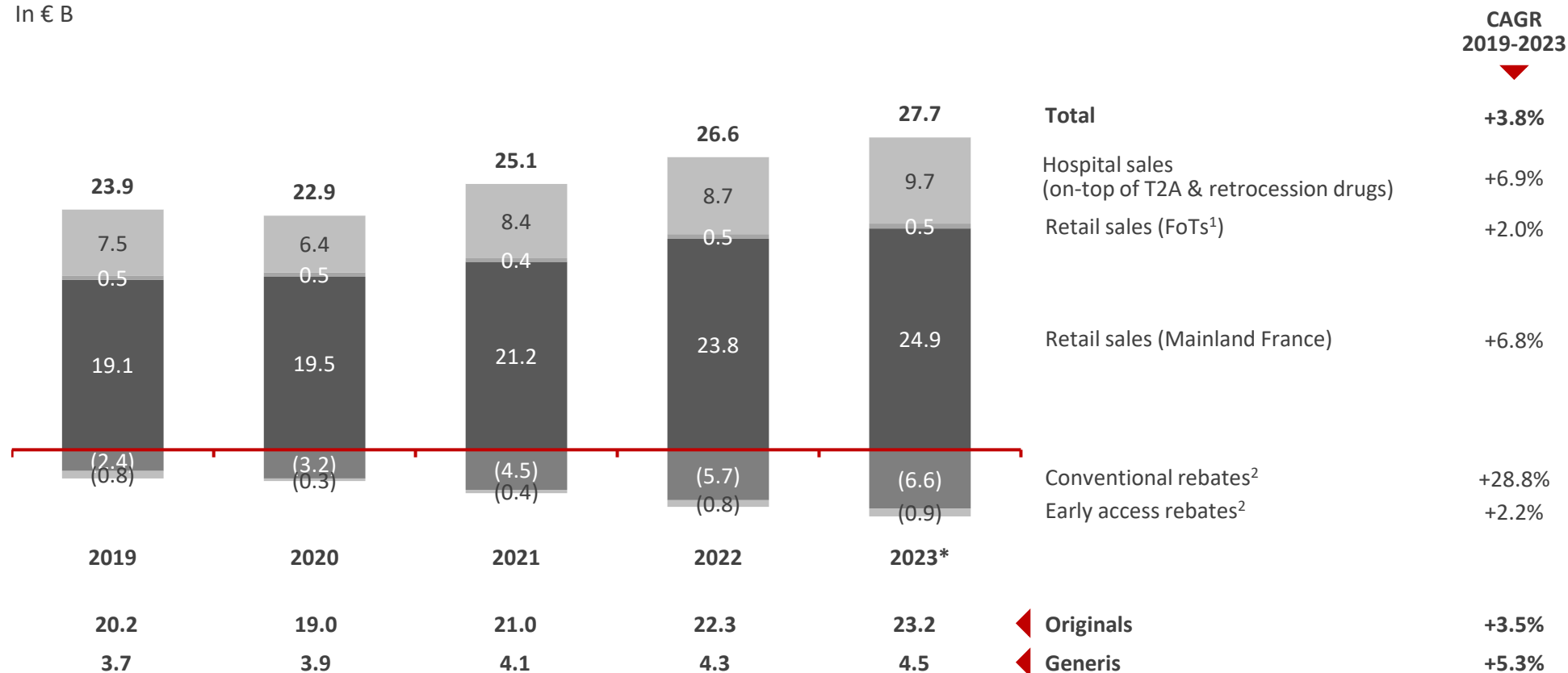
Sources: LFSS 2019 to 2024 – Smart Pharma Consulting analyses

¹ National objective for National Health Insurance Fund expenditure – ² Trigger threshold of the clawback

Drugs expenditure, net of conventional & early access rebates, was estimated at € 27.7 B for 2023, representing a +3.8% CAGR over 2019 – 2023 (+3.5% CAGR for originals vs. + 5.3% for generics)

3 Drugs expenditure, net of conventional and early access rebates (2019 – 2023)

In € B



* Estimates, based on GERS data and interviews

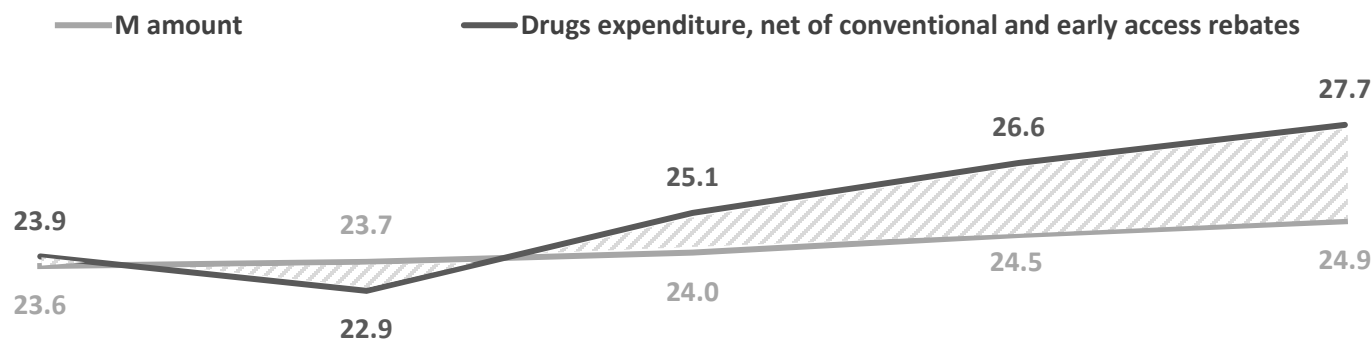
Sources: GERS – Leem – Gemme – CEPS annual report (January 2024) – Smart Pharma Consulting analyses and estimates

¹ French Overseas Territories – ² Money reimbursed by pharma companies to the National Health Insurance Fund, based on a predefined agreement (e.g., amount corresponding to the difference between the official drug price list and the net price negotiated with the CEPS). These rebates do not apply to generics. These conventional rebates apply to certain original drugs, but not to generic, nor to biosimilars

Drugs expenditure, net of conventional and early access rebates, systematically exceeded the “M amount” between 2019 and 2023 (except in 2020)

4 Clawback – Savings for the National Health Insurance Fund (2019 – 2023)

In € B



	2019	2020	2021	2022	2023*
Overrun amount	▶ € 0.3 B	N/A	▶ € 1.2 B	▶ € 2.1 B	▶ € 2.8 B
Overrun < 0.5 pt (50% clawback)	▶ € 0.1 B	-	▶ € 0.1 B	▶ € 0.1 B	▶ € 0.1 B
From 0.5 to 1 pt (60% clawback)	▶ € 0.1 B	-	▶ € 0.1 B	▶ € 0.1 B	▶ € 0.1 B
Overrun > 1 pt (70% clawback)	▶ < € 0.1 B	-	▶ € 0.6 B	▶ € 1.3 B	▶ € 1.7 B
Clawback before rebates	▶ € 0.2 B	-	▶ € 0.8 B	▶ € 1.4 B	▶ € 1.9 B
Tax-exempt rebates (deductions)	▶ -20.0%	-	▶ -13.0%	▶ -15.1%	▶ -15.0%
Clawback after rebates	▶ € 0.1 B	-	▶ € 0.7 B	▶ € 1.2 B	▶ € 1.6 B

* Estimates, based on GERS data and interviews

The government and the Leem have signed an agreement to keep the capping of the clawback at € 1.6 B in 2025, while generics clawback will be capped at 1.75% of their sales (vs. 2% in 2024)

4 Clawback – Regulatory changes expected (2024 – 2028)

		2024	2025	2026	2027	2028
M amount		<ul style="list-style-type: none"> € 26.4 B (art. 28, LFSS 2024) 	<ul style="list-style-type: none"> € 27.9 B¹ (art. 9, PLFSS 2025)* 			
Clawback capping	All drugs	<ul style="list-style-type: none"> Total clawback capped at € 1.6 B, provided € 600 M savings are generated through proper use and delisting of drugs (agreement signed between the government and the Leem, Nov. 21, 2024)* Clawback capped at 10% of the basis for calculating the contribution M for each pharma company (art. 28, LFSS 2024) 				
	Generics	<ul style="list-style-type: none"> Clawback capped at 2% of generics gross sales (art. 28, LFSS 2024) 	<ul style="list-style-type: none"> Clawback capped at 1.75% of generics gross sales (amendment to the PLFSS 2025 adopted by the Senate on Nov. 21, 2024)* 		<ul style="list-style-type: none"> Clawback capped for each pharma company at 12% of the total net amount reimbursed by the National Health Insurance Fund for their drugs (article 28, LFSS 2024) 	
Clawback calculation					<ul style="list-style-type: none"> Clawback based on net amount reimbursed by the National Health Insurance Fund, and no longer on sales declared by pharma companies (art. 28, LFSS 2024) 90% tax rate applied to the difference between the net amount reimbursed by the National Health Fund and the “M amount”, and no longer the progressive scale ranging from 50% to 70% depending on the extent of the “M amount” exceeded (art. 28, LFSS 2024) 	

* Pending LFSS 2025 vote by the French Parliament

Sources: PLFSS 2025 – LFSS 2024 – KPMG (January 2024) – Agreement signed between the government and the Leem (November 21, 2024) – Smart Pharma Consulting analyses

¹ Considering the sales declared by pharma companies (that would have corresponded to € 23.3 B reimbursed by the National health Insurance if the reform of the calculation of the clawback rebate had not been postponed conforming to the agreement signed between the government and the Leem on November 21, 2024)

Under discussion measures may have significant impact on pharma companies (e.g., revised calculation of the clawback, stock shortages sanctions, savings on drugs, etc.)

Key measures under discussion*

PLFSS ¹ 2025			Other measures
ONDAM ² (art. 27)	Clawback rebates (art. 9)	Drugs supply (art. 19)	Drugs reimbursement
<ul style="list-style-type: none"> ▪ ONDAM set at a total amount of € 263.9 B for 2025 (+2.8% vs. revised 2024) including: <ul style="list-style-type: none"> – The funding of measures resulting from conventional negotiations, such as the medical convention signed in June 2024 – The compensation to health and medico-social facilities for the increase in the CNRACL³ contributions – An increase in retirement benefits (annual revaluation postponed in July 2025) – € 5 B savings (on health products, biology, imaging, daily allowances, anti-fraud measures, etc.) 	<ul style="list-style-type: none"> ▪ Modification of the basis for calculating drugs expenditure <ul style="list-style-type: none"> – Exclusion of the EMI⁴ / ERI⁵ – Integration of mirror marketing authorizations and off-label prescriptions ▪ Exemption for new companies (created for less than 1 year) ▪ When a drug is transferred from a pharma company to another: calculation based on the official date of the transfer ▪ Adjustments planned to respect the deadlines for notification and payment of the contribution ▪ M amount set at € 27.9 B (based on sales declared) 	<ul style="list-style-type: none"> ▪ Improvement of operational systems aimed at preventing drug shortages ▪ Strengthened penalties against market players failing to respect their obligations in terms of drug supply, with sanctions increased from 30% to 50% of drug sales, up to a limit of € 5 M (vs. a € 1 M ceiling currently applied) ▪ Publication of financial sanction decisions on the ANSM website for one year 	<ul style="list-style-type: none"> ▪ Drugs reimbursement rates by the National Health System dropped by 5 pts, with reimbursement rates decreased from 65% to 60%, from 30% to 25% and from 15% to 10% ▪ This measure will be acted through ministerial decree
			Public savings on drugs
			<ul style="list-style-type: none"> ▪ Commitment given by the Leem to the government to generate € 600 M savings in return for capping the clawback at € 1.6 B in 2024 and 2025 (through proper use and delisting of drugs)

* As of November 25, 2024

Sources: PLFSS 2025 – Le Figaro (November 18, 2024) – Agreement signed between the government and the Leem (November 21, 2024) – Smart Pharma Consulting analyses

¹ Projet de loi de la Sécurité Sociale: Social Security Financing Act Project – ² National objective for National Health Insurance Fund expenditure – ³ Caisse nationale de retraite des agents des collectivités locales: National Pension Fund for local authority agents – ⁴ Ecart médicament indemnisable: compensable medication gap – ⁵ Ecart rétrocession indemnisable: compensable retrocession gap

Unpredictability of cost-containment measures and low regulated drug prices strongly impair the French pharma market attractiveness, representing an obstacle to R&D and industrial investment

Key Takeaways

1. With a public deficit amounting to 6.1% of GDP and a public debt of 112.9% of GDP in 2024, France is far from EU objectives (3% and 60%, respectively)

2. With a GDP growth estimated to range from +1.1% to +1.5% by 2028, public income should not increase much, unless the government takes new levy measures

3. The National Health Insurance Fund deficit should reach € 18 B in 2024 (+67% vs. 2023)



4. The government can activate 4 levers to regulate drugs public spending: P&R¹, rebates, clawback and medical control

5. When compared to the four largest pharma markets in Europe, France has the lowest prices for drugs, irrespective of whether drugs are genericized or not

6. The clawback will be capped at € 1.6 B in 2024 and 2025, provided € 600 M savings are generated by pharma companies through proper use and delisting of drugs

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

Market Insights Series

- 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

Healthcare Costs Regulation in France

Better Insights for Better Anticipation

This short document highlights some key insights regarding the regulation of healthcare costs in France:

- Key macroeconomic indicators (2019-2024)
- National Health Insurance Fund deficit (2009-2024)
- Government's levers to regulate drug public spending
- Drugs price international comparisons (2023)
- Drugs rebates to the National Health Insurance Fund (2022)
- Clawback definition, principles and calculation (2019-2023)
- Key regulatory changes expected (2024-2028)

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](#):
 - 43 articles
 - 87 position papers covering the following topics:
 1. Market Insights
 2. Strategy
 3. Market Access
 4. Medical Affairs
 5. Marketing
 6. Sales Force Effectiveness
 7. Management & Trainings
- 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