Smart Pharma
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The French Pharma Market 2022 – 2027

BUSINESS REPORT

Strategic Implications for Pharma Companies

Excerpts

March 2023

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Executive Summary

Glossary

This report analyzes the current situation and the key trends on the French Pharma market by the end of 2027 to provide pharma companies with key strategic insights

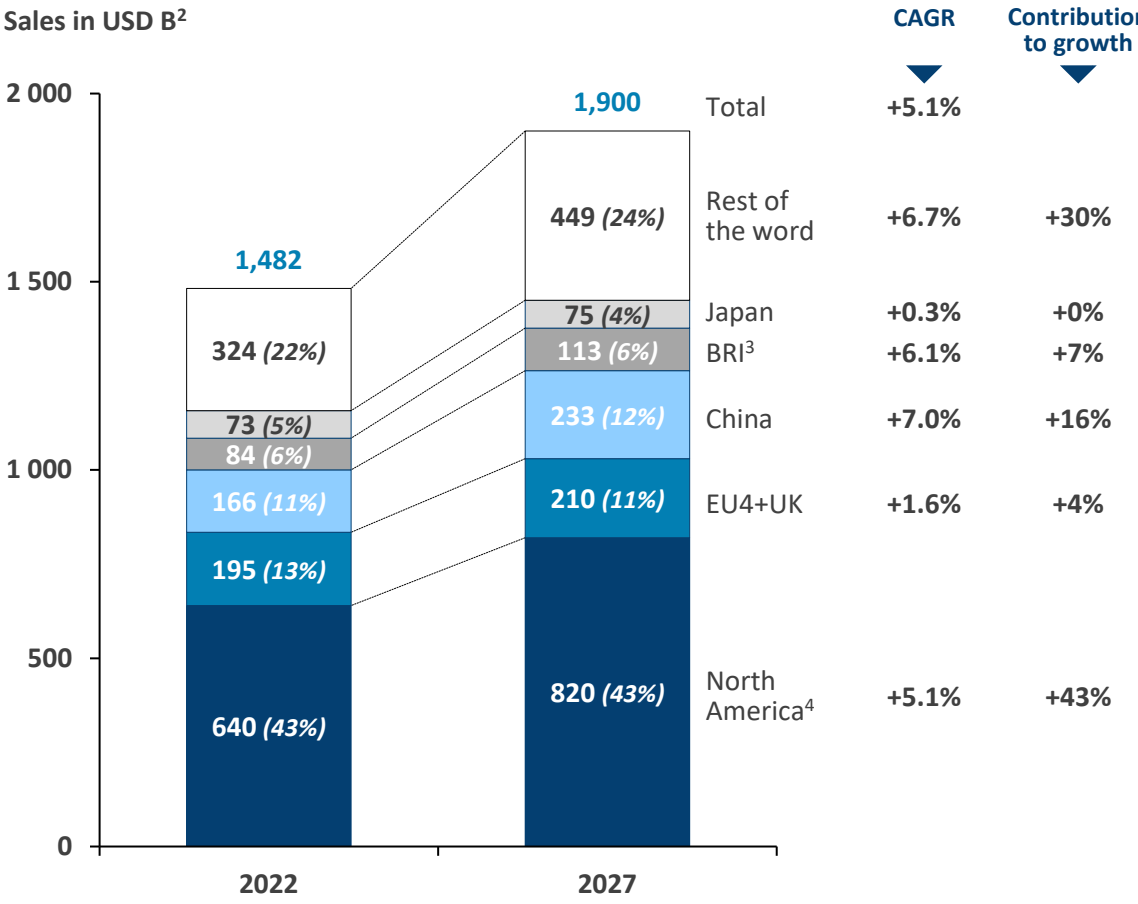
2022 – 2027 French pharma market prospects & strategic implications

- Despite an ever-tougher environment, the French pharma market should remain a key priority for most of pharma groups
- Smart Pharma Consulting proposes to address the following key issues related to the French healthcare system and pharma market evolution by the end of 2027, to better grasp its strategic impacts for pharma companies

- How is the French healthcare system organized at national and regional levels?
- What are the key recent measures introduced by health authorities and their impact?
- What are the behavioral trends of key stakeholders and their impact by 2027?
- What are the estimated sales forecasts by strategic segment on the French pharma market by 2027?
- What could be the strategic and organizational implications for pharma companies by 2027?

Sales of EU4[1]+UK should grow slowly by 2027 due to stringent cost containment measures leading to a two-point decrease of their weight in the global pharmaceutical market

Global pharmaceutical market size and growth by geographic area (2022 – 2027)



	CAGR	Contribution to growth
Total	+5.1%	
Rest of the word	+6.7%	+30%
Japan	+0.3%	+0%
BRI[3]	+6.1%	+7%
China	+7.0%	+16%
EU4+UK	+1.6%	+4%
North America[4]	+5.1%	+43%

- The global pharma market is expected to grow with a **CAGR of +5.1%** by 2027 including the impact of Covid-19, that should lead to **higher pressure** on **prices** worldwide in the next 5 years
- **EU4+UK** countries account together for only 13% of the global pharma market:
  - Germany: 4%
  - France: 3%
  - Italy: 2%
  - UK: 2%
  - Spain: 2%

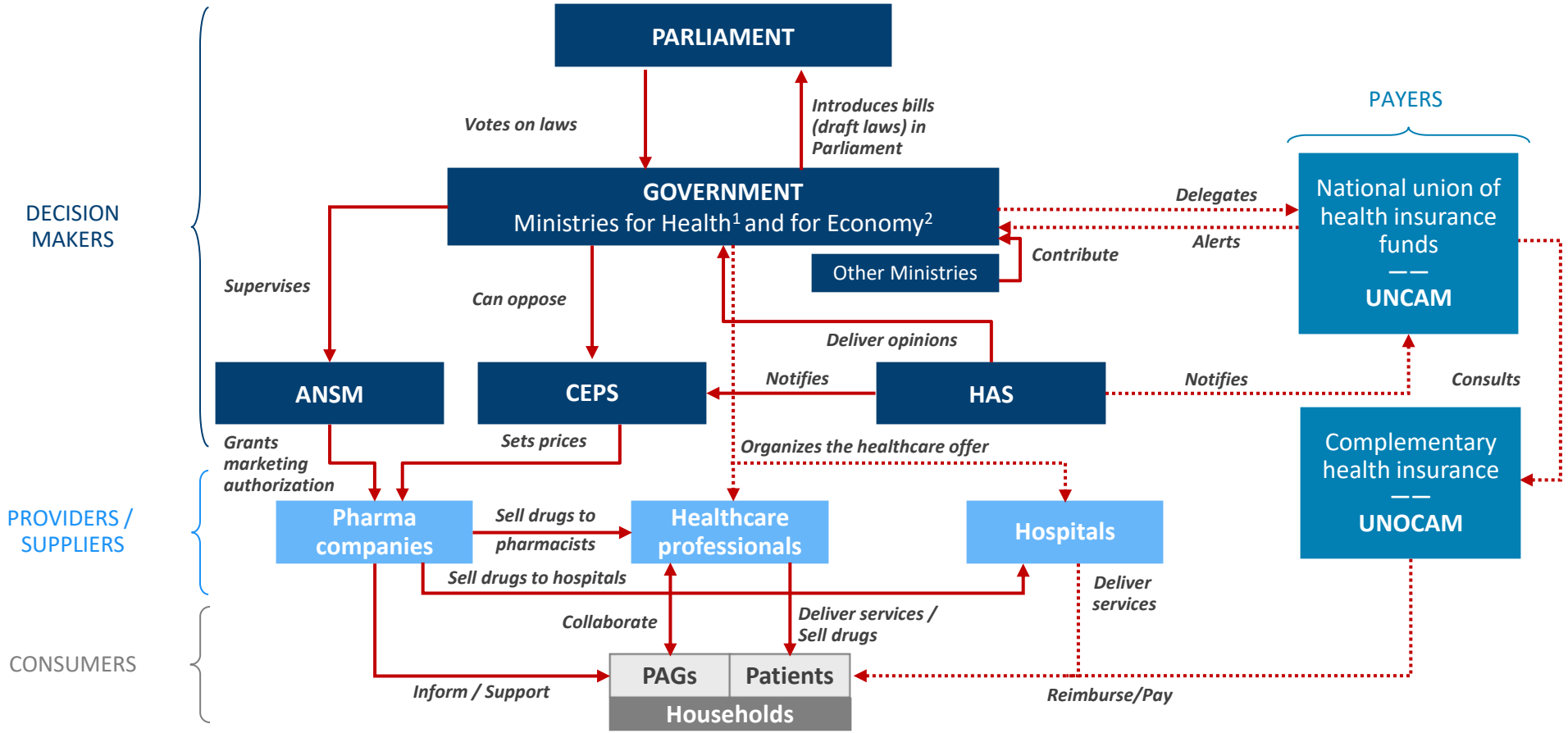
  and should see their **weight drop by 2 points** by 2027, **due** to higher **price pressure** than in the average of the other countries
- **North America** should continue to weigh for 43% of the global pharma market in value and contribute to **43% to worldwide market growth** over the 2022 – 2027 period

Sources: IQVIA Institute (January 2023) – Smart Pharma Consulting estimates

[1] France, Germany, Italy, Spain – [2] Ex-factory price before rebates – [3] Brazil, Russia, India – [4] USA and Canada accounting for 41% and 2%, respectively

Stakeholders in the French healthcare system can be divided according to their role as decision makers, payers, providers / suppliers and consumers

Mapping of key stakeholders

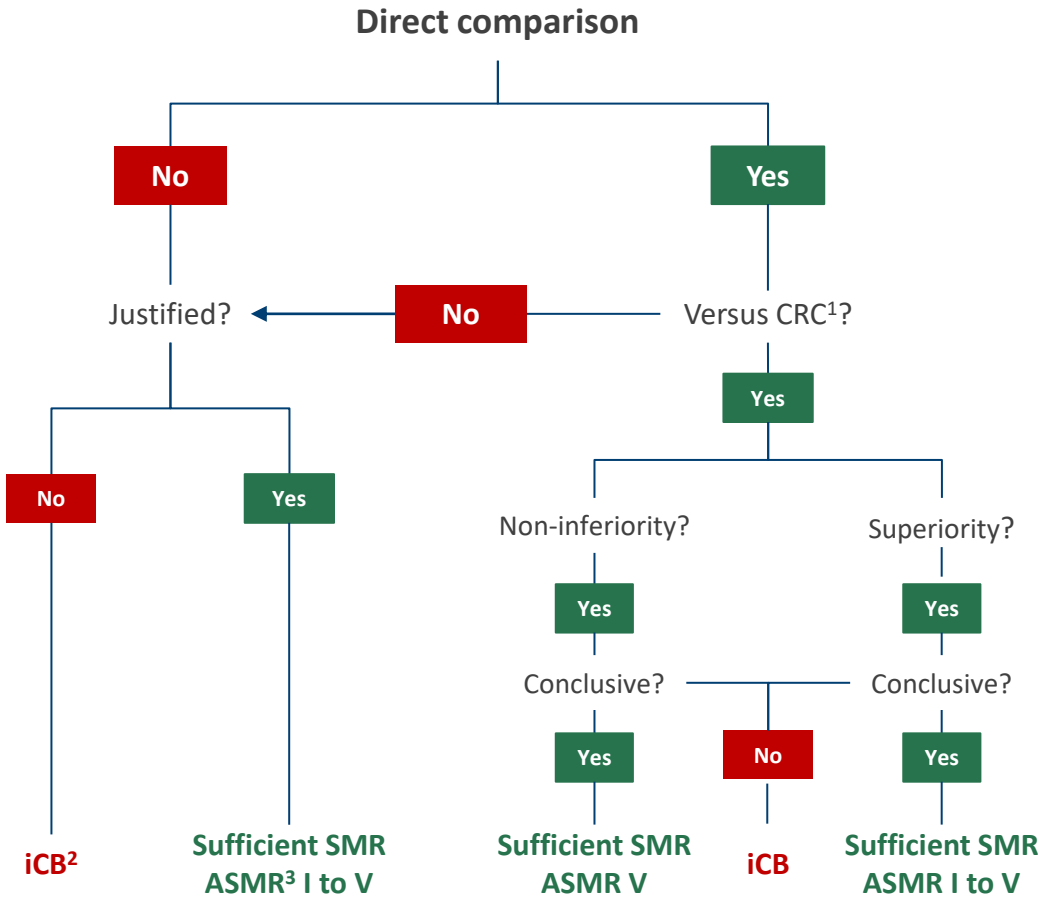


Sources: Smart Pharma Consulting analyses

[1] The exact name of this ministry is: Ministry of Solidarity and Health – [2] The exact name of this ministry is the Ministry for the Economy and Finance which includes the budget and the industry

To assess the therapeutic progress of a product, the Transparency Committee will expect direct comparison – whenever possible – in terms of efficacy and safety with existing relevant therapies

Transparency Committee – ASMR (Clinical added value) assessment



- The Transparency Committee (TC) will particularly pay attention to the following criteria, in view of medical need:
  - The quality of the demonstration:
    - The choice of comparator(s)
    - The methodological quality of the study
    - The appropriateness of the population included
    - The relevance and significance of clinical endpoints
  - The effect size in terms of clinical efficacy, quality of life and safety in view of the demonstration robustness
  - The clinical relevance of this effect compared to clinically relevant comparators
- Double-blind randomized trials are the gold-standard
- The absence of direct comparison to comparator must be justified and can be accepted by the TC in certain situations
- The absence of a direct comparison, which the TC believes was possible, may lead to an ASMR V
- The TC reasoning presented in this table is not fixed and is adapted to the context of each evaluation

Sources: Transparency Committee doctrine (February 2023) – Smart Pharma Consulting analyses

[1] Clinically Relevant Comparator – [2] Insufficient Clinical Benefit – [3] Clinical Added Value

The framework agreement signed between CEPS and Leem in March 2021 aimed at improving patient access to innovation, encouraging investments in France and simplifying access processes

CEPS – Framework agreement signed with the Leem (2021 – 2024)

Context & objectives

- Framework agreement signed on **March 5, 2021,** by the **CEPS** and the **Leem Chairman**, in the presence of the Minister of Health and the Delegate to the Minister of Economy in charge of Industry
- This new agreement, that replaces the previous one which had been signed in 2016, has been concluded for a **3-year period**, i.e., until March 5, 2024
- **3 main objectives** pursued:
  - Improve **patient access** to **innovation**
  - Encourage **productive investments** in France
  - Simplify **market access** processes

Patient access to innovation

Innovative drugs

- Guidance on the duration of effect of comparators, the inclusion on uncertainty, the setting of rebates and the splitting of payments

Orphan drugs

- Possibility of renegotiating the terms of conventional rebates if target population evolves
- Commitment to come to a contractual amendment within 6 months with an adjusted budget package
- Fluidification of price negotiation

Drugs that meet public health needs

- Possibility for ASMR IV drugs meeting a non- even partially-covered medical need to access to an EU price[1]

Productive investments in France

Support for investment and export

- Creation of a specific chapter intended to support for investment and export
- Authorization for investing pharma companies to proactively meet with the CEPS President to be informed of conventional terms

Pricing counterparties

- Possibility of granting an EU price[1] to ASMR I to III drugs whose manufacturing activities[2] are mainly carried out in France
- List price stability guaranteed over 2 years (renewable once) for products manufactured in Europe (notably in France) for which more than 60% of volumes are exported

Market access processes

Fast-track

- Access guaranteed within a maximum period of 15 days[3] for:
  - ASMR I to III with dominant efficiency
  - ASMR IV with dominant efficiency & allowing savings
  - ASMR V with prices lower than comparators

Price stability and predictability

- 5-year stability of the EU price[1] for ASMR I to III drugs, covering both list and net prices

Transparency

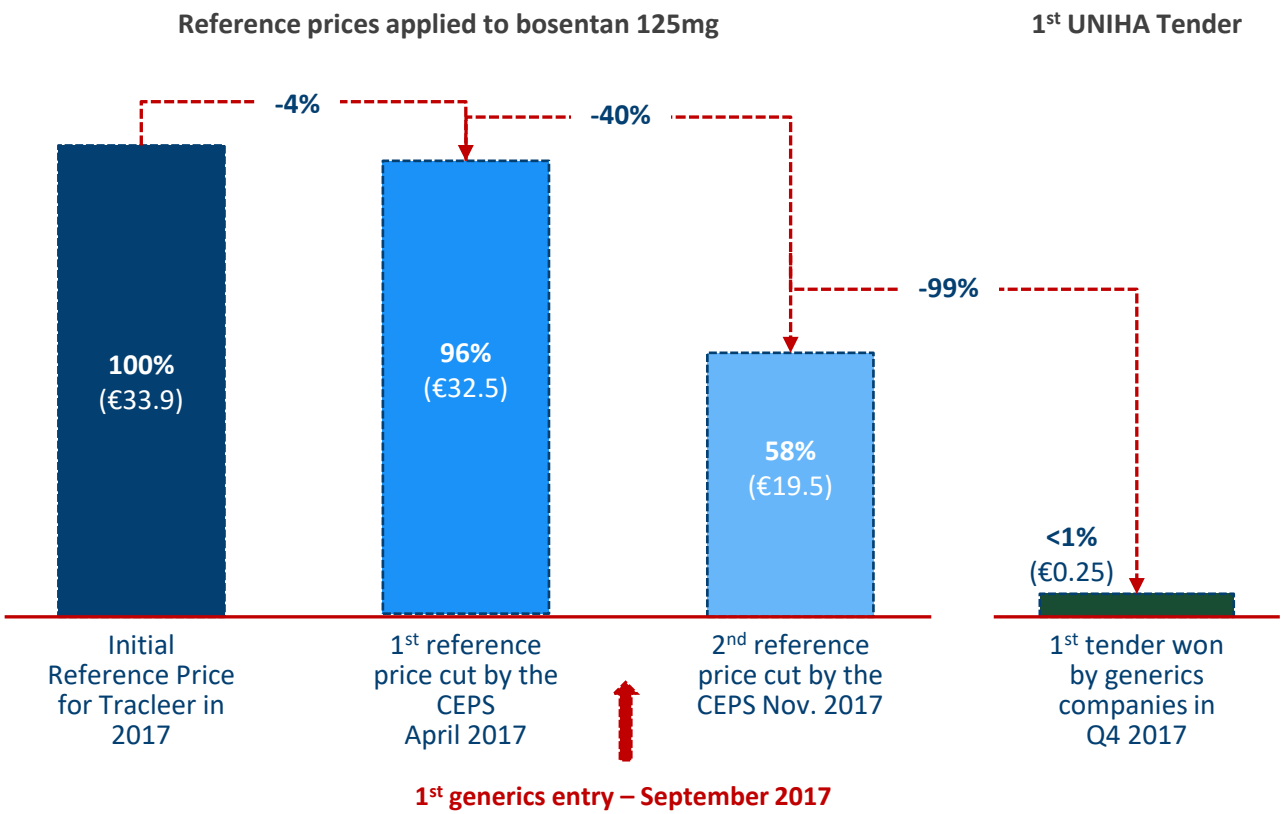
- Statement by pharma companies of the amount of both R&D investment made, and public incentives received

Sources: Framework agreement signed between CEPS and Leem (March 5, 2021), and update (April 2022) – Smart Pharma Consulting analyses

[1] In this case, French price cannot be lower than the lowest price in the rest of EU4+UK – [2] Manufacturing of active components, finished goods and/or packaging – [3] From the date of receipt of the economic interest note by the CEPS

Bosentan net price has dropped drastically as soon as the 1st call for tender, enabling the best bidder to discard competitors while taking the risk to make this "market" little or even non profitable

CEPS – Hospital generics pricing: Bosentan (Tracleer)



Comments

- For bosentan, the purchasers did not really value the quality of the dossier
- **UNIHA**[1] and the **AGEPS**[2] account for **80%** of the total bosentan market
- The UNIHA market has been won at €0.25, Teva offered €0.50, and the originator price was €19
- The prices on generics **should go up** for the future calls for tender
- The prices should not remain at this level, which is **unlikely to generate profits**
- Such a **drastic** drop was not expected by Actelion (Janssen)
- Few small accounts do not list generics of bosentan
- Janssen did not discount beyond -75%

Sources: Business Intelligence – Smart Pharma Consulting analyses

[1] Purchasing group for Regional Teaching hospitals and other public hospitals –
[2] Purchasing group for largest public hospitals in Paris and close suburbs

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

CEPS – Prices, margins and rebates for reimbursable drugs

	Originator without TFR[1]	Originator with TFR	Generic without TFR	Generic with TFR
Ex-factory price	▪ Price negotiated / set by the CEPS ▪ Generics are priced 60% below originator price at patent expiry ▪ Originator price is cut by 20% after generics entry or at patent expiry			
Wholesalers' margins	▪ Minimum of € 0.30 per pack if ex-factory price below € 4.33 ▪ 6.93% of ex-factory price if ex-factory price from € 4.33 to € 468.97 ▪ 0% beyond € 468.97, representing a maximum of € 32.50 margin per sold unit			
Pharmacists' margins	▪ Variable margin: – 10.0% of ex-factory price below € 1.92 – 7.0% from € 1.92 to € 22.90 – 5.5% from € 22.91 to € 150.00 – 5.0% from € 150.01 to € 1,930.00 – 0% above € 1,930.00 ▪ Dispensing fees (VAT excluded): – € 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]	▪ Maximum legal rebate: 2.5% of ex-factory price	▪ Maximum legal rebate: 40% of ex-factory price, since September 2014 (17% before)		
	▪ Possibility to add up to 100% of the wholesaler margin in case of direct sales			

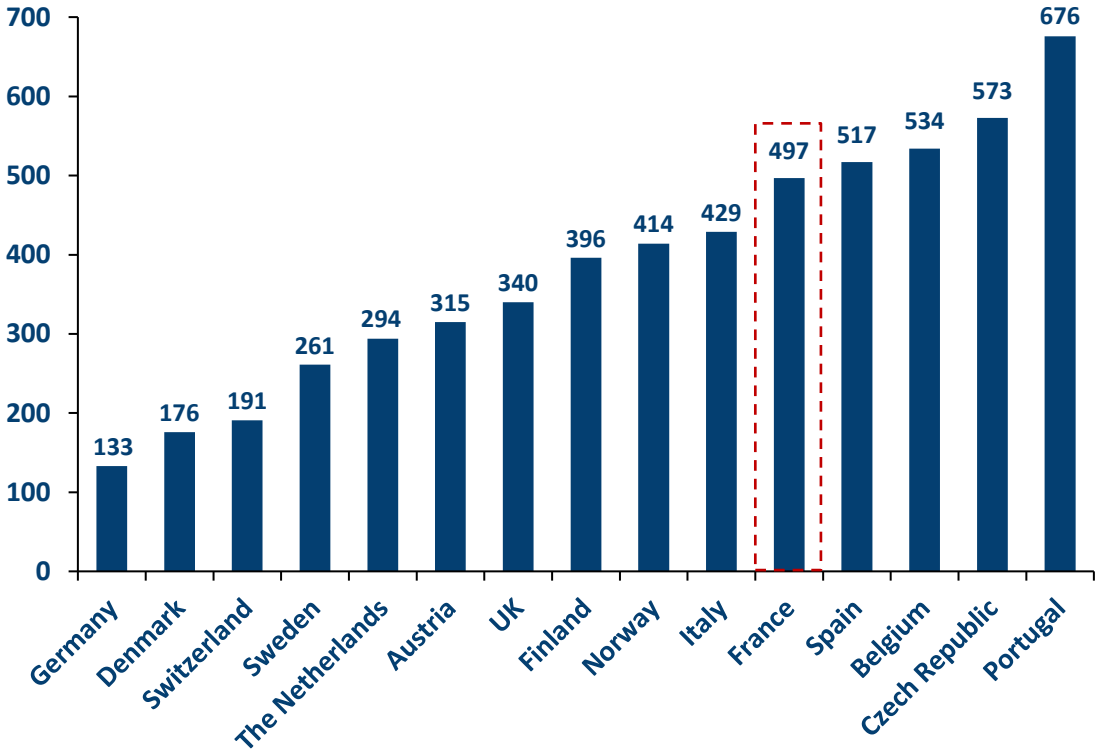
Sources: CEPS annual report (December 2022) – National pharmaceutical agreement (March 2022) – Legifrance – Ameli – Leem – Smart Pharma Consulting analyses

[1] Tarif Forfaitaire de Responsabilité (Reference price) – [2] Including cooperation and other commercial rebates

In France, pharma companies and patients must wait ~16 months after marketing authorization to get a new drug reimbursed and launched[1]

Average time to market access – European comparisons

Mean time in days between marketing authorization and price and reimbursement[1,2]



2022 analysis based on a sample of 160 products approved by EMA (European Medicines Agency) between January 2017 and December 2020

- In Europe, the delay between marketing authorization of a drug and its availability on the market may vary widely, due to the time required to obtain its inclusion on reimbursement list and a price agreement
- In countries such as Italy, France or Spain, this delay exceeds the 180 days recommended by the European Commission
- An important delay may be harmful both for patients who do not have full access to innovative therapies and for companies which face a loss of revenues
- The UK and Germany have smaller delays since the price and reimbursement negotiations occur once the product has reached the market

Sources: Patients W.A.I.T. Indicator – EFPIA (July 2022) – Smart Pharma Consulting analyses

[1] Excluding early access programs for breakthrough innovations, except for France – [2] For drugs receiving their first marketing authorization between 2017 and 2020

Since the introduction of the T2A reform in 2004, the allocation of resources of public and private hospitals is based on the nature and on the volume of the activities carried out by each hospital

Hospital funding system: Activity-based funding (T2A) principles

Objectives	Means	Expected results
Increase the efficiency of hospitals	▪ Converge funding systems to be able to compare public and private sectors ▪ Gradually implement the T2A to facilitate the adaptation of both structures and players ▪ Harmonize funding arrangements between public and private sectors ▪ Expand the clarity and the visibility of the role of the players, for both managers and supervisors	Greater involvement of medical players in financing
Address the inequity of resources allocation across structures		Accountability of health players
Optimize the funding of the most active structures		Development of quality management and medico-economic tools
		Fairness of treatments between public and private sectors

Major drawback

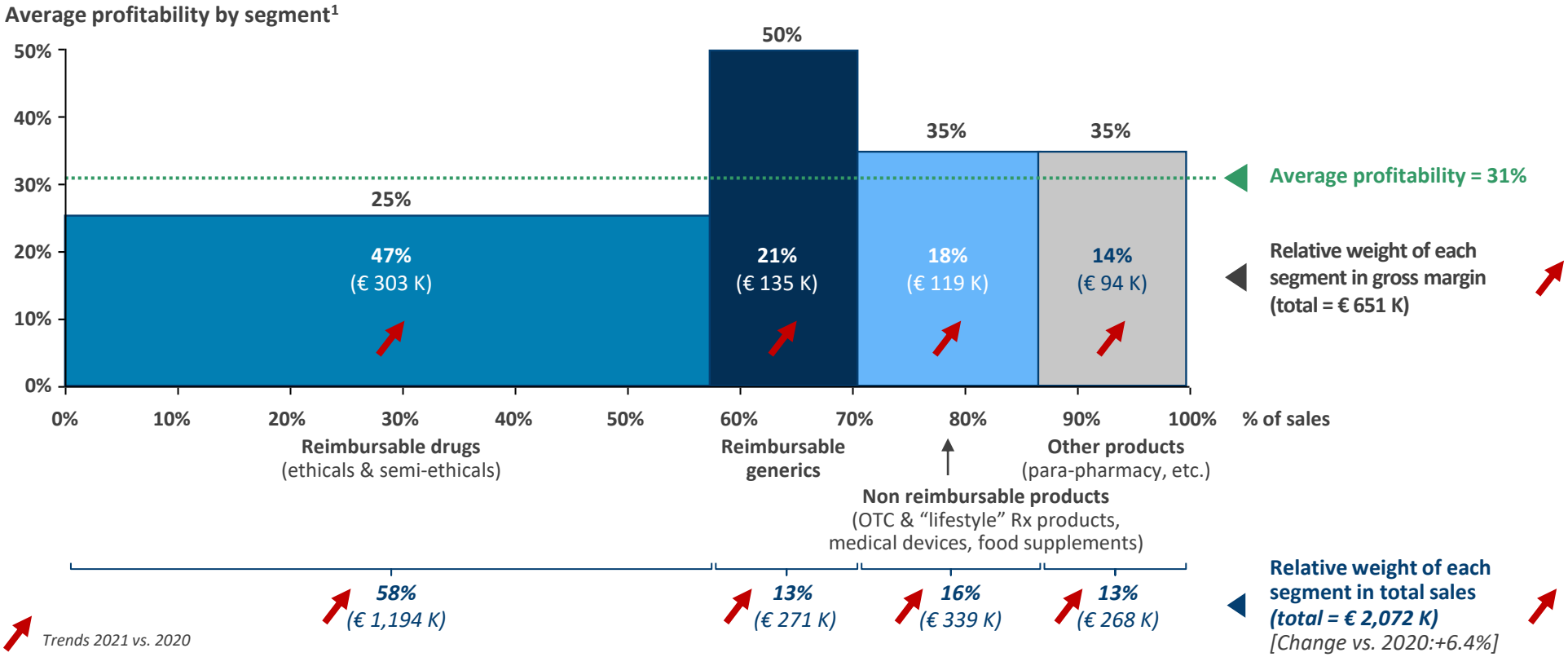
- The T2A has led to an inflationary effect; hospitals being prompted to increase their level of activities and notably of the most profitable medical procedures, for maintaining adequate funding
- "MyHealth2022" aimed to cap T2A at 50% of total hospital funding (T2A still represented 67.5% in 2021)

Sources: French Ministry of Health website (January 2023) – Senate committee of inquiry (2021) – Smart Pharma Consulting analyses

In 2021, originators accounted for ~58% of the retail pharmacies sales on average, and for ~47% of their gross margin

Economic structure of retail pharmacies in France (2021)

Average annual turnover of a retail pharmacy in 2021: € 2,072 K
(public price excluding VAT)



Note: Dispensing fees, ROSP and fee for services accounted for ~67% of the retail pharmacy margin on reimbursed drugs

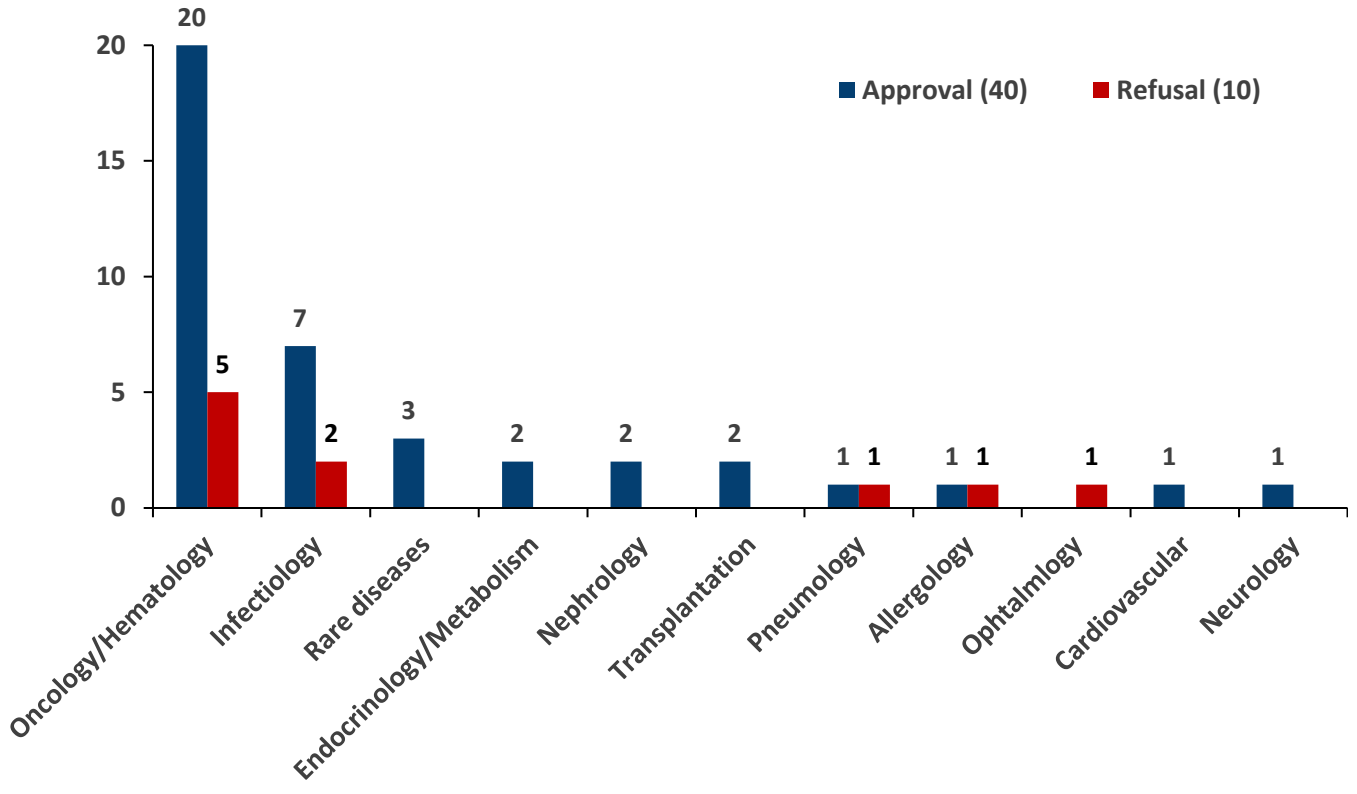
Sources: CGP Experts Comptables (2022) – Smart Pharma Consulting estimates

[1] Including legal margin, rebates, commercial agreements and remuneration for pharmaceutical services, notably those corresponding to the public health objectives (e.g., generics substitution objectives, pharmaceutical interviews with patients, etc.)

In March 2022, 10 months after the implementation of the EAP, 40 applications were approved and 10 refused, mainly in the field of oncology/hematology

Early Access Programs (3/3)

Distribution of EAP decisions by therapeutic area (March 2022)

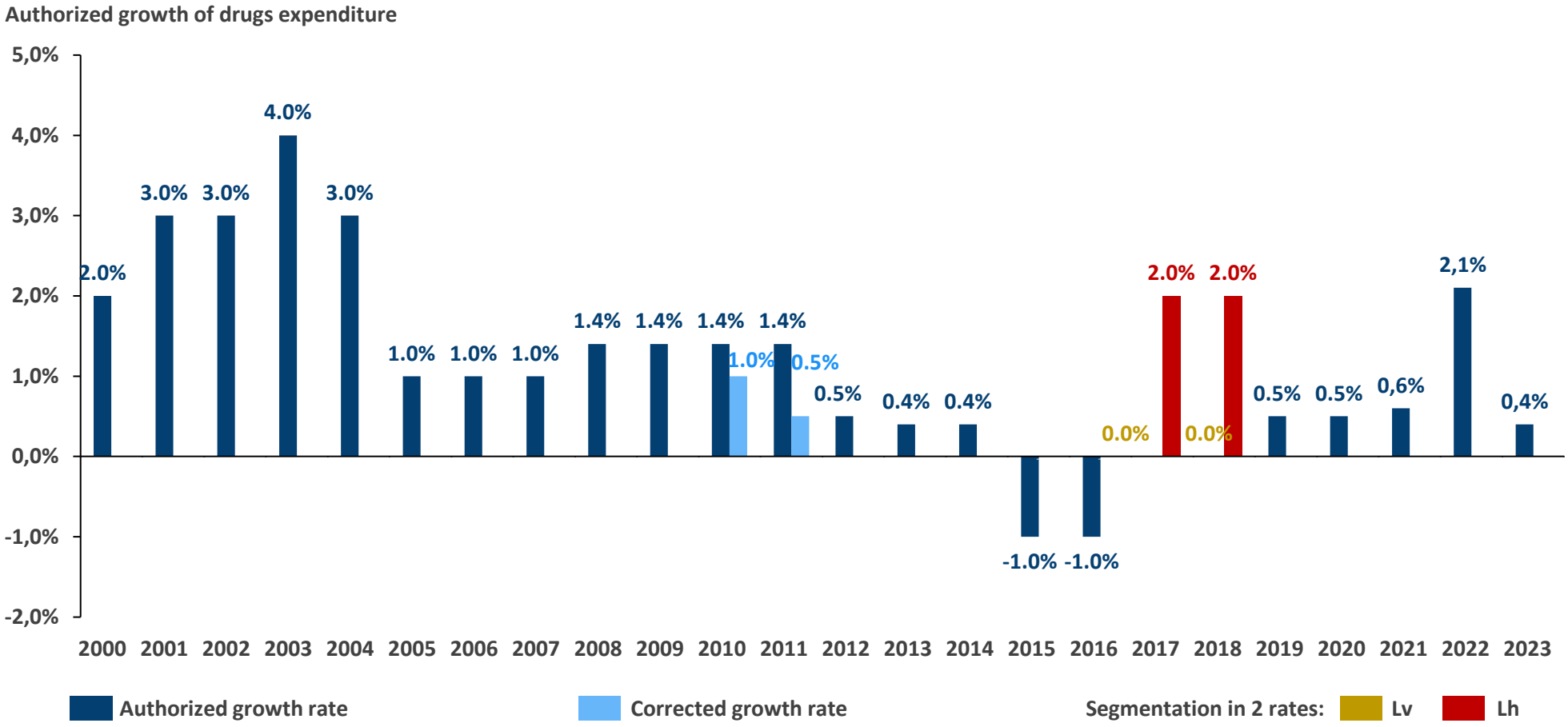


- As of March 2022, 10 months after the implementation of the EAP, **40 applications** have been **approved** and **10 denied**
- Processing times **averaged 60 days** for EAP applications and **35 days** for Covid-related drugs...
- ...well within the **90-day regulatory timeframe**

Sources: ANSM publication (May 2022) – Smart Pharma Consulting analyses

The growth rate of drug expenditures has been set at +0.4% for the year 2023

Safeguard clause – Authorized growth of drugs expenditure (2000-2023)



Sources: Gemme – Légifrance – Smart Pharma Consulting analyses

Launched in December 2019, the Health Data Hub[1] is a French platform designed to cross-reference existing health databases for medical research purposes

Health Data Hub

SNDS[2]
National Health Data System

- **PMSI**: Information Systems Medicalization Program (Hospital data)
- **SNIIRAM**: National Health Insurance Inter-Plan Information System (National Health Insurance Fund data)
- **CNSA**: National Solidarity Fund for Autonomy (Disability data from MDPH)
- **CépiDC-Inserm**: Electronic certification of causes of death (Medical causes of death)
- **Complementary health insurance companies** (Sample of data)

Aggregating and making these data available to promote studies, research or evaluation of a public interest nature and contributing to the :

- Information on health
- Implementation of health policies
- Knowledge of health expenditures
- Information of professionals and institutions about their activities
- Innovation in the fields of health and medico-social care

Definition
- New French **health data platform**, created in **December 2019**, that allows to cross-reference existing health database and thus facilitate their use for research and development purposes

Objective
- Based on the **Artificial Intelligence**, create a platform for accessing and sharing data, in the service of **health research** and **innovation**

Pros
- **Health issues**: improving research and development
- **Competitive advantage** at international level for research and innovation

Cons
- **Sensitive** and **personal data** that can be used if there is a public interest and after the CNIL's[3] consent
- Data hosted by **Microsoft**: **exposure to US law** (Cloud Act): following the concerns of the CNIL and the Government, the Health Data Hub **is seeking a new European or French host by 2025**

Implication for pharma companies
- **Perspectives of interest** at each stage of the drug or medical device value chain, from research to development, including monitoring the use of healthcare products in real life and organizing care pathways
- **Access to data**, not accessible as of today
- Additional place to forge **new links and partnership relations** with the players of the ecosystem, whether public or private

Sources: Health Data Hub website (January 2023), CNIL (February 2021) – "Health Data Hub : 6 questions sur la plateforme de données de santé et sa polémique", Numerama (June 2020) – "Le Health Data Hub : quelles opportunités pour l'industrie pharmaceutique ?", Alcimed (July 2020) – Smart Pharma Consulting analyses

[1] Also named PDS (Plateforme des données de santé) – [2] Système National des Données de Santé – [3] Commission Nationale de l'Informatique et des Libertés (National commission for information technology and civil liberties)

The Digital Health Agency, which replaced the ASIP-Santé[1] in December 2019, supports the digital transition of the healthcare system alongside all the players in the ecosystem

Digital Health Agency

AGENCE DU NUMÉRIQUE EN SANTÉ
La transformation commence ici

- The agency aims to make digital technology a key asset to move towards a more equitable, qualitative and efficient system, which is materialized through its 3 fundamental roles:

1 Regulator

- Improve digital performance through common rules of regulation and exchange

2 Operator

- Design major national e-programs for an efficient and supportive public health service

3 Promoter and developer

- Stimulate, support and evaluate all e-health initiatives to help them grow

The Digital Health Agency is helping those working in the field in the use of e-health tools and services

HCPs
Provision of secure, communicating solutions and value-added services

Health facilities
Work to protect health data, coordinate teams, modernize information systems, identify resources and patients and manage incidents

Medical and social facilities
Accelerate the deployment and systematization of digital uses by encouraging decompartmentalization with the health sector

Manufacturers
Assist throughout the projects, from the compliance to the referencing of the solutions, operated in the respect of the requirements and stakes

Regions
Support the development of e-health in regions

Governance

Anne PREVOT
General Manager

Jacques LUCAS
President

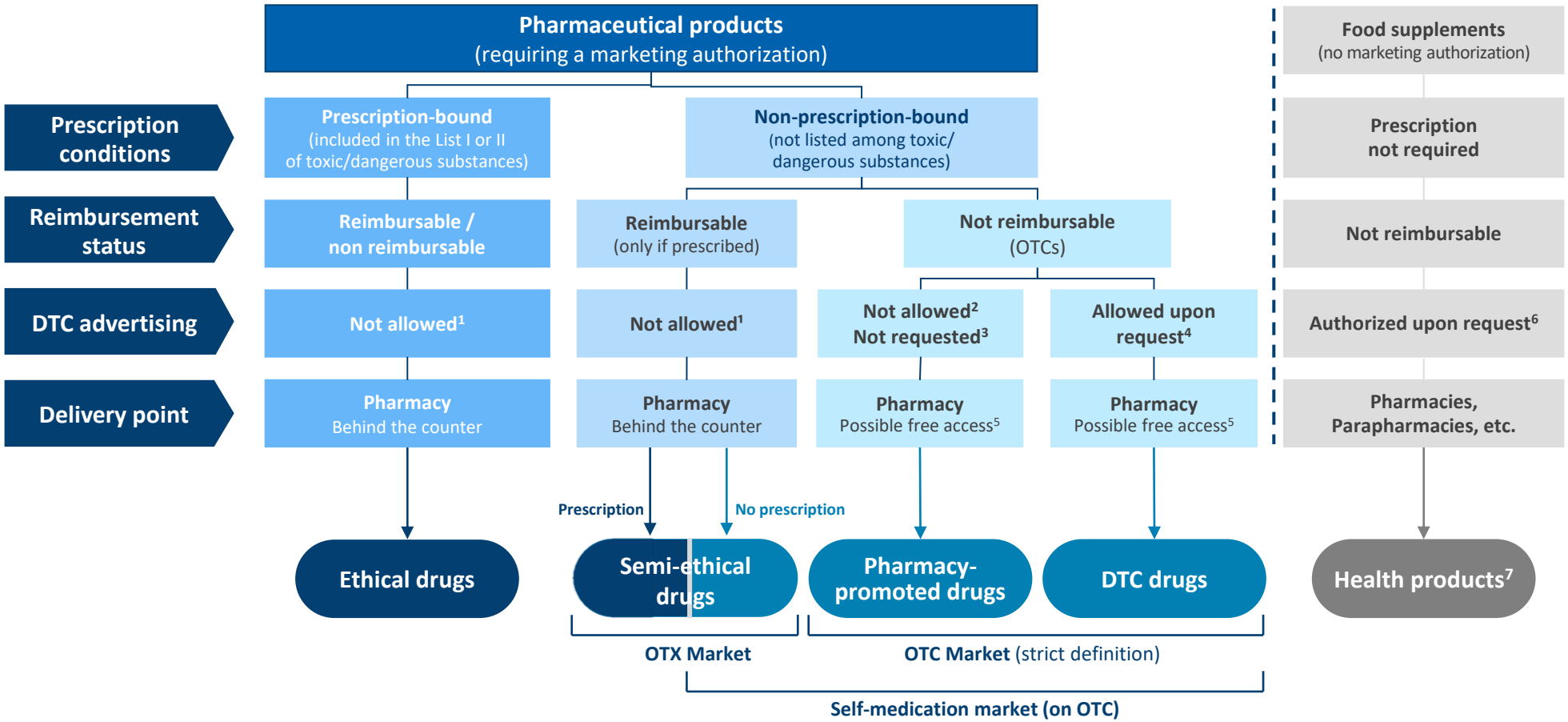
Jean-Pierre AQUINO
Alternate President

Sources: esanté.gouv.fr (February 2023) – TICSanté (December 2019) – Digital Health Agency Activity Report 2021 (2022) – Smart Pharma Consulting analyses

[1] Agence des systèmes d'information partagé de santé: Shared Health Information Systems Agency

Pharmaceutical products can be split into prescription-bound and non-prescription-bound drugs, knowing that some of the prescribed drugs are not reimbursed

Classification of pharmaceutical products in France



Note: OTC = Over-the-counter, OTX = combination of prescription (RX) and over-the-counter (OTC), DTC = Direct to consumer

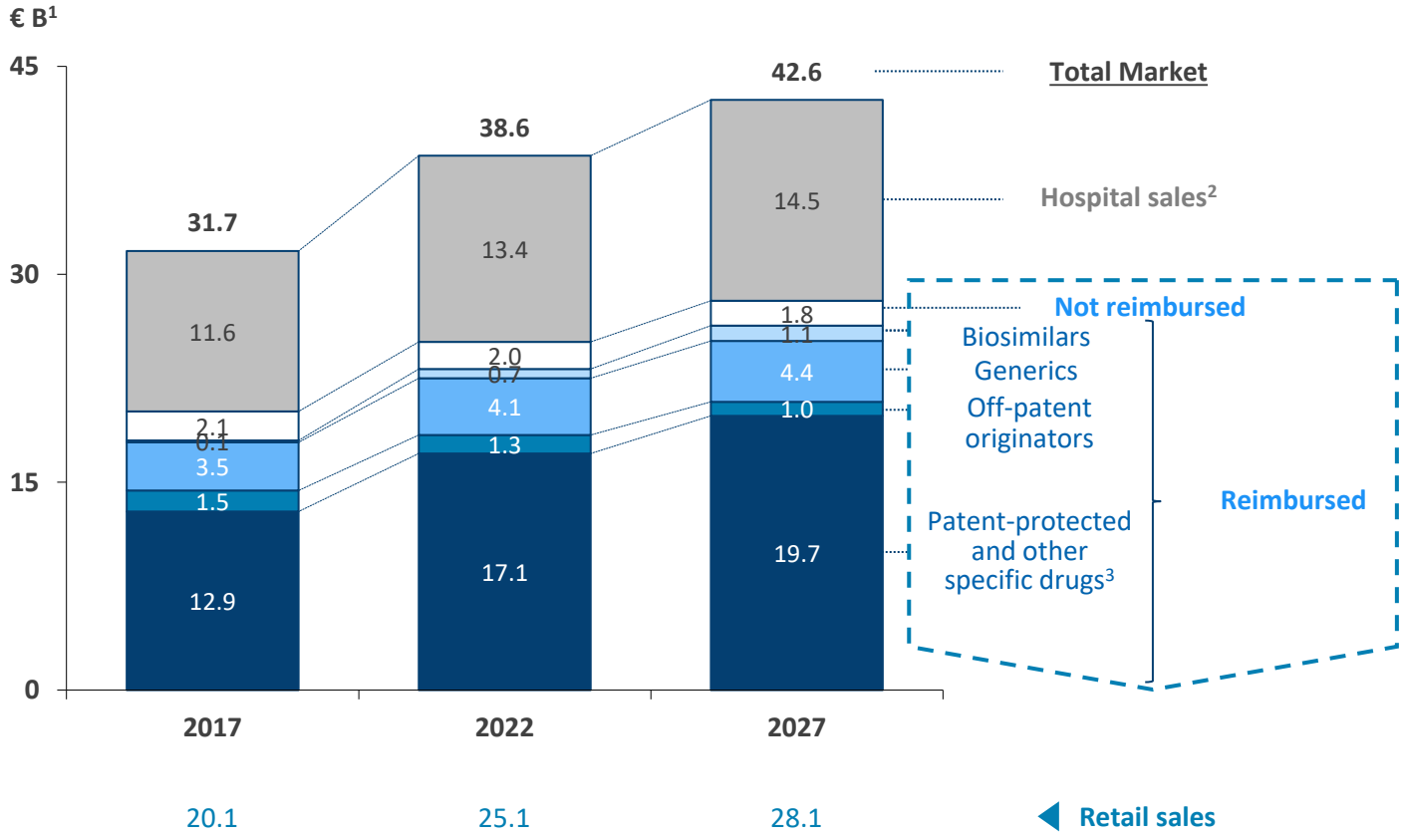
Sources: ANSM – DGCCRF – Smart Pharma Consulting analyses

[1] Rare exceptions (e.g., vaccines) – [2] Psychotropic or narcotic drugs – [3] When the pharma company does not wish to communicate to the general public – [4] Whatever the claims – [5] Possibility of "free access" within the retail pharmacy for certain OTC products – [6] Only for claims relating to healing, alleviating or preventing diseases – [7] Other than drugs and pharmaceutical products

By 2027, the French pharmaceutical market should be mainly driven by patent-protected drugs, generics and biosimilars delivered in retail pharmacies

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

Gross price



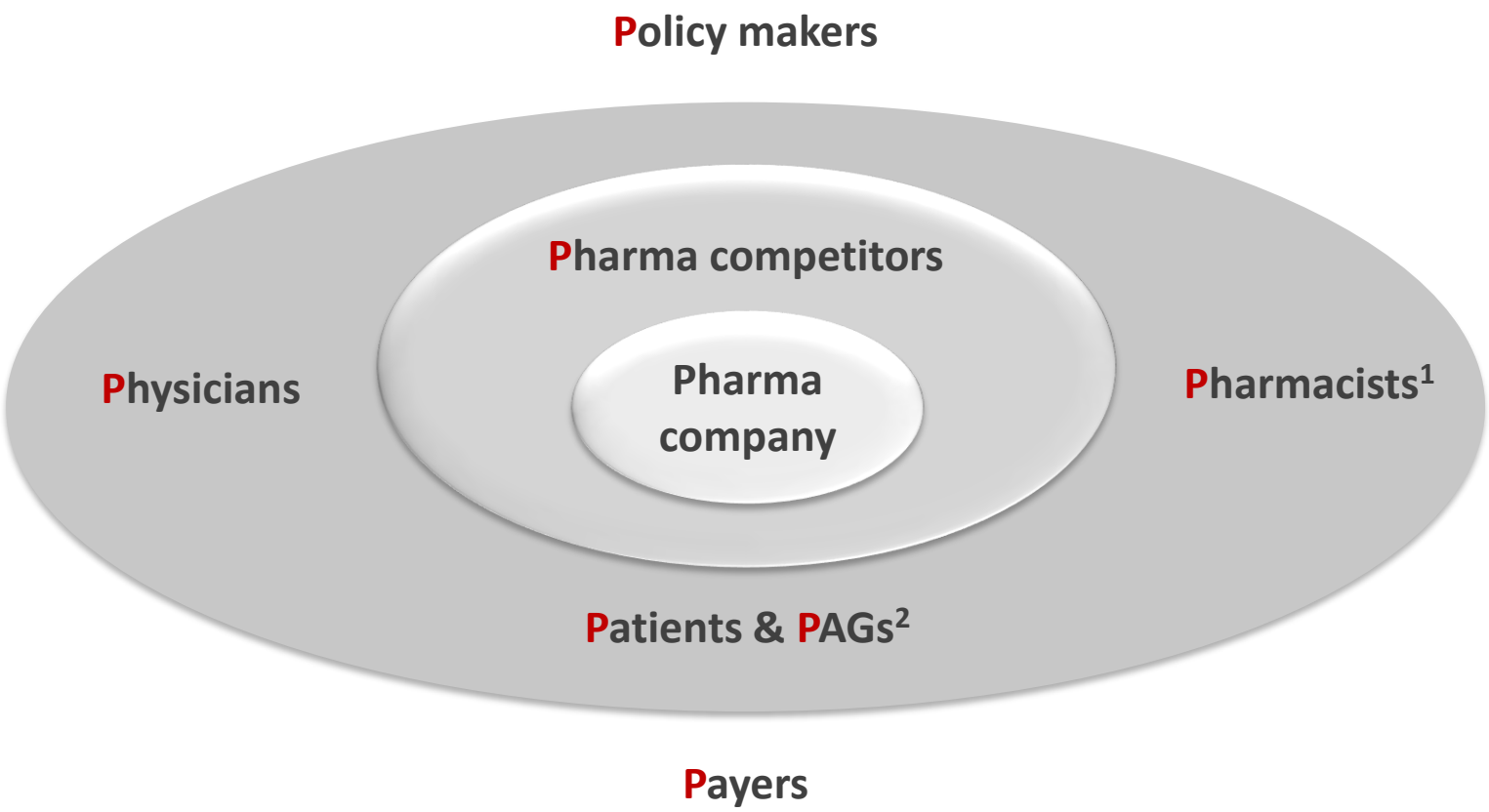
	CAGR[4] 2017-2022	CAGR 2022-2027
Total Market	**+4.0%**	**+2.0%**
Hospital sales[2]	+3.0%	+1.5%
Not reimbursed	**-1.4%**	**-1.7%**
Biosimilars	+36.6%	+10.8%
Generics	+3.4%	+1.4%
Off-patent originators	-2.8%	-5.5%
Reimbursed	**+5.2%**	**+2.6%**
Patent-protected and other specific drugs[3]	+5.8%	+3.0%
Retail sales	**+4.5%**	**+2.3%**
20.1	25.1	28.1

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 reassigned 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

Pharmaceutical companies' strategic priorities by 2027 will be linked with the behavior of the "7 Ps" stakeholders

The 7 Ps



Sources: Smart Pharma Consulting analyses

[1] Pharmacists also play the role of purchasers, and their importance will keep on increasing in the upcoming years, either on the open care or the hospital segments – [2] Patient Advocacy Groups

Policy makers & payers might introduce new containment measures to secure the sustainability of the healthcare system over time

Stakeholder behavioral trends: Policy makers & Payers (1/3)

2022 – 2027 Trends

Stricter control of reimbursed drugs expenditure

Measures to boost generics, biosimilars & hybrids

- Strong willingness to better control the National Health Insurance Fund deficit, over the long-term:
  - 2023 deficit set at € 7.1 B (vs. € 21.4 B in 2022)
  - 2023 ONDAM set at € 244.1 B (+3.3% vs. 2022)
  - 2023 safeguard clause triggered for a:
    - M value of € 24.6 B (+0.4% vs. 2022)
    - Z[1] value of € 2.2 B (+2.8% vs. 2022)
- More “aggressive price” regulation of marketed drugs
- Possible amendment of the T2A system
- Better cost management of on-top of T2A products

General implications

- Tighter reimbursement restrictions:
  - Number of indications
  - Volume per indication
  - Number of targeted patients
- Drug cost containment measures:
  - Managed care agreements for innovative drugs
  - Stronger pressure on established brands:
    - Accelerated price cuts over time for reimbursed drugs
    - New measure to boost generics, biosimilars and hybrids (e.g., incentives for hospital and office-based physicians to prescribe biosimilars, for retail pharmacists to substitute)
    - Will to reduce / collect high-level rebates received by retail pharmacists from generics companies
  - Faster decrease of the ceiling price set by the CEPS for on top of T2A hospital drugs

Sources: Smart Pharma Consulting analyses

[1] Financial regulation mechanism introduced by the LFSS 2020 concerning on-top of T2A medical devices

Pharma companies must position their products, services and themselves to be perceived by policy makers and payers as offering superior value than competition

Strategic priorities induced by Policy makers & Payers behavioral trends

Behavioral trends	Strategic priorities for pharma companies
1 Stricter control of reimbursed drugs expenditure	Enhance the global value proposition (incl. corporate identity, product and service offering) through: – Dedicated corporate reputation programs targeted at policy makers and government – Generation of data vs. standards of care, real world data and … – … high quality medico-economic studies (whenever relevant)
2 Measures to boost generics, biosimilars & hybrids	
3 Earlier and broader access to innovation	Leverage the opportunity offered by fast-track process and public health national plans (e.g., cancer, rare diseases, etc.)
4 Healthcare system reorganization	Participate to working groups with health authorities and other stakeholders to: – Facilitate the change management – Ensure it will benefit or be neutral on pharma company performance
5 Promotion of investments in France	Increase or maintain R&D activities to be in a more favorable position to negotiate drugs' price, and weigh – very carefully – the pros and cons before deciding to produce in France

Sources: Smart Pharma Consulting analyses

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

The Smart Pharma Business Reports

- Our business reports have in common to:
  - Be well-documented with recent facts and figures
  - Highlight the key points to better understand situations
  - Propose in-depth analyses
  - Determine the business implications for stakeholders

The French Pharma Market 2022 – 2027 Prospects

- This report has been conceived as a working tool to:
  - Strengthen and align the level of knowledge and understanding of the French pharma market and its key trends by the executives of French affiliates
  - Facilitate the communication, with correspondents of affiliates at the European and/or Global headquarters, regarding the specificities and major trends in France
  - Support the strategic decisions over the next 5 years
- The purchase of this report includes:
  - A two-hour working session to address one or more specific points covered in this report
  - A free access for all collaborators of the pharma group

Smart Pharma Consulting Editions

- Besides our consulting activities which take 85% of our time, we are engaged in sharing our knowledge and thoughts through our:
  - Teaching and training activities
  - Publication of articles, booklets, books and business reports
- Since 2012, we have published **20 business reports** covering the following topics:
  - French healthcare system and pharma market (2023, 2021, 2019, 2017, 2015, 2014, 2013, 2012)
  - Market access and drug valuation (2016)
  - French generics market (2017, 2016, 2014, 2012)
  - Global biosimilars drugs market (2015, 2012)
  - Best pharma performers (2015)
  - French pharma distribution (2015, 2012)
  - Digital marketing (2012)
  - French OTC market (2012)
- We expect that this new publication will be helpful

Best regards,

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