
THE FRENCH SOCIAL SECURITY FINANCE BILL (PLFSS) & MEDICINES

An explanation

September 2023

THE FRENCH SOCIAL SECURITY FINANCE BILL (PLFSS) & MEDICINES

AN EXPLANATION p.3

**KEY POINTS
AND KEY FIGURES** p.4

10 KEY QUESTIONS ON THE FRENCH SOCIAL SECURITY FINANCE ACT (LFSS) DEFINITION, FRAMEWORK AND CHALLENGES

1. What actually is a PLFSS? p.5
2. How is the LFSS structured? p.5
3. What is the best way to navigate through the LFSS appendices? p.6
4. How is the PLFSS prepared?
By whom and when? p.6
5. Why is this law voted on
by Parliament every year? p.8
6. How do medicines fit into the LFSS? p.8
7. Focus on the Ondam p.8
8. To what extent is the LFSS a channel
for pharmaceutical regulation? p.9
9. Why is there a deviation between
the law and the reality
of the healthcare system? p.9
10. Why is rebasing necessary? p.11

FACT SHEETS TO GO FURTHER

Fact Sheet 1

Medicines: a regulated economy
(2012-2022) p.14

Fact Sheet 2

The four levers
of medicines regulation p.17

Fact Sheet 3

Medicine prices in France p.23

Fact Sheet 4

Taxation of medicines in France p.28

Fact Sheet 5

An explanation of the 2023
“Financing and Regulation
of Health Products” mission p.31

**LEEM POINTS OF
CONCERN REGARDING
THE PLFSS FOR 2024** p.32

**ANNEX 1
RESOURCES** p.33

**ANNEX 2
PLFSS GLOSSARY** p.34

THE FRENCH SOCIAL SECURITY FINANCE BILL (PLFSS) & MEDICINES

An explanation

Why have we produced this kit?

This document has been produced to explain and demystify the mechanisms of the French Social Security Finance Act (LFSS) and provide a clearer understanding of the issues at stake in this annual legislation, which sets the financial conditions governing access to medicines in France.

Who is it intended for?

This kit is intended for anyone who wants to understand the workings of the LFSS and how it impacts the economics of medicines.

Why is Leem an appropriate organisation to explain the PLFSS?

As the French Pharmaceutical Companies Association, Leem and its team of expert health economists have analysed the PLFSS every year since its introduction in 1996. As an essential contributor to discussions around the PLFSS, Leem has produced this document to share its expertise.

5 key points

to understand how medicines are impacted by the LFSS

- ➔ **The parliamentary debates that accompany the PLFSS provide the only opportunity for public discussion** on medicines policy in France.
- ➔ During this process, the regulator sets a figure **for 'acceptable' growth** in the *National health insurance (Assurance maladie)* expenditure on medicines, the overall level of savings required, and the measures required to achieve those figures.
- ➔ **Decisions taken in the context of the LFSS for the current year (year N) form the basis in government forecasts made during the previous year (year N-1).** The absence of any subsequent adjustment provision to reflect actual data prevents the level of regulation being matched to the actual level of expenditure.
- ➔ The LFSS is the legislative channel through which **Members of Parliament vote on the "Montant M" (M amount); the revenue threshold above which all pharmaceutical companies must contribute a very large proportion of revenue generated to the National health insurance scheme** (see page 13).
- ➔ Leem pays very close attention to the methodology used to set "Montant M", and continues to make the case for the multi-year expenditure trajectory to be readjusted to reflect actual expenditure.

5 key figures

to measure the economic pressure imposed on medicines

Over €3bn > Medicines are required to make the highest contribution to *National health insurance savings*. Taken together, the measures imposed to regulate medicines when preparing the Ondam for 2023 represented more than €3 billion; an amount that is grossly under-estimated by Annex 5 to the PLFSS 2023 (which indicates €1.1 billion in savings for all healthcare products, including €150 million from the safeguard clause: an estimate that bears no relation to actual market trends).

9,1% > Total revenue generated by regulated medicines is expected to account for 9.1% of expenditure within the Ondam scope for 2022 (excluding Covid-19 measures) compared with 11.7% for 2010.

€1.1bn > The safeguard clause amount is expected to be €1.1 billion for 2022, even higher than the previous historically high level of 2021 (€680m). As a corrective mechanism designed to mitigate non-compliance with the Ondam, this clause has, in a roundabout way, become a regulatory instrument in its own right to the point of constituting a new tax in disguise, the impact of which more than cancels out the Government's policy of tax relief.

53% > Medical cost containment through prescription control (the relevance of prescriptions) achieved only 53% of the savings forecast for 2019, while targets for savings via price cuts or clawback payments made by manufacturers have been regularly exceeded.

6 > Over and above the general taxation regime, France applies six industry-specific taxes and fees to pharmaceutical companies (even without taking account of the safeguard clause); a figure much higher than for equivalent schemes in neighbouring countries: Spain has 3, Germany 1 and the UK 0.

10 key questions on the French Social Security Finance Act (LFSS)

Definition • Framework • Challenges



1 • What actually is a PLFSS?

A Social Security Finance Bill (PLFSS, for “*Projet de loi de financement de la Sécurité sociale*”) is a piece of draft legislation introduced annually in France to set the budgetary provisions for the national Social Security system ; i.e. it determines the general conditions for balancing the annual finances, and sets expenditure targets for the following year.

Once the bill has been adopted by majority vote in Parliament it passes into law as the Social Security Finance Act (LFSS) and is promulgated in the Official Journal (*Journal Officiel*) in December of each year. So the LFSS for 2024 will be published in December 2023.

It was the constitutional amendment of 22 February 1996 that brought the control of the nation’s social security finances, and with it the LFSS, into the remit of Parliament.

Social Security covers 5 areas of social policy, structured formally into “branches :

- “illness” (which includes medicines) ;
- “family” ;
- “pensions”;
- “occupational accidents and illnesses”;
- “independent living”.

Social Security also has a funding function (collection of social security contributions, debt management, etc.).

2 • How is the LFSS structured?

Since 2022, reform of the organic law governing Social Security Finance Acts, the LFSS has been structured into **3 sections**:

→ **The original first section** relates to **the previous financial year**. Following the vote to adopt the organic law of 14 March 2022, this section will be presented in the form of a budget review act on 1 June each year, quite separately from the other three parts. The budget review act for 2023 will be voted on in June 2024 ;

→ **The new first section** relates to **the current financial year**, and takes the form of an amending finance act;

→ **The new second section** (formerly the third section) sets **the forecasts of social security revenue**;

→ **The new third section** (formerly the fourth section) sets **the social security spending** target known as the Ondam.

Ten mandatory annexes to the legal text are forwarded to the social partners and Parliament before the bill is tabled for debate by the National Assembly.

The reform of the organic law governing Social Security Financing Acts introduced by Member of Parliament Thomas Mesnier in 2021 and adopted on 14 March 2022 changed the structure of the LFSS: the former first section of the LFSS (in respect of the financial year ended on 31 December of the previous year) is now the subject of a specific piece of legislation, which is debated in the spring of the following year: the Social Security Accounts Approval Act.

3• What is the best way to navigate through the LFSS appendices?

How to identify references to medicines policy within the text of the PLFSS:

- **Open Appendix 5** (budget balances and savings measures) and go to the **Ondam Construction paragraph**.
- **Search** (<ctrl> F), the text of the PLFSS using the “*médicament*” and “*enveloppe M*” (the M amount envelope) keys words and view **the explanatory statement** in each article.
- Then, for each article, **go to Appendix 9 (budget impact study)**, which explains why the Government is submitting each measure to Parliament, possible alternatives and the impact on the Social Security accounts (savings or additional expenditure relative to the previous year).
- **Lastly, read Appendix 1 (the social security policy evaluation report)** to track the trends of multiple indicators (especially the results for savings from medical cost containment through prescription control).

4• How is the PLFSS developed? By whom and when?

Many stakeholders are involved throughout the year in the process of developing the Social Security Finance Bill. The key period of the bill is the autumn, when both chambers of Parliament debate the text.

GOOD TO KNOW

As with finance acts, **the LFSS comprises four sections:**

- 1. The mandatory section** containing those measures that must be included and reviewed in the text: the Social Security financial balance, revenue and expenditure and the balance tables.
- 1. The exclusive section** containing measures that are not mandatory, but must appear exclusively in the LFSS: allocation of exclusive revenue from different schemes, no-netting by the State.
- 3. The shared section** containing measures that can be included: change in the tax base or tax rate, improvements in the information provided to Parliament, etc.
- 4. The prohibited section** containing the ‘welfare riders’; measures that could be proposed in the PLFSS, but would have no impact on the social security finances, which remain the purpose of the LFSS.

THE TIMEFRAME OF THE PLFSS

APRIL

JUNE

SEPTEMBER



THE DSS DEVELOPS TREND SCENARIOS AND SAVINGS MEASURES 1 JUNE: PUBLICATION OF SECTION 1 RELATING TO THE PREVIOUS FINANCIAL YEAR

MATIGNON (PM'S OFFICE) / ELYSÉE (PRESIDENT'S OFFICE) ARBITRATE

BEFORE THE SUMMER

A range of bodies involved in social security provision submit a first draft to the Government (usually before the summer):

- The Social Security Department (DSS) develops trend scenarios, proposes a range of reforms and savings measures, and is responsible for drafting the bill;
- The *Direction générale de l'offre de soins* (Health-care services Department), *Direction générale de la santé* (Health Department), *Direction générale de l'administration et de la fonction publique* (Administration and public service Department), *Direction du budget* (Budget Department), *Direction générale des entreprises* (Enterprise and Industry department), *Caisse nationale de l'Assurance maladie* (National Health Insurance Fund), or any other competent governmental body may also contribute to the process of drafting the text.

DURING THE SUMMER

The Government validates the initial balances and policy directions of the PLFSS. The bill is then prepared in greater detail and drafted by the government departments.

SEPTEMBER TO EARLY OCTOBER

The Prime Minister and the President validate the budgetary balances of Finance Bills (PLFs) and PLFSS, as well as the specific measures covered by the text, in a number of interministerial meetings (RIMs) held between August and September. On completion of these meetings, the bill is reviewed by the Council of Ministers in late September/early October, before submission to Parliament in early October.

OCTOBER TO DECEMBER

Following consideration by Parliament between October and December, the text is evaluated several times throughout the following year.

THE FOLLOWING SPRING

Every year, the *Cour des comptes* (Court of Audit) publishes two reports that have a structural impact on social security issues: the general social security system accounts certification report in the spring of the following year (essentially an accounting report), and the report on implementation of social security finance laws, which formulates proposals for reforms designed to maintain a viable forward trajectory for the public accounts. At the same time as this report is published, the Government presents a bill approving the Social Security accounts for the financial year to 31 December of the previous year. This bill contains the provisions previously presented in Section 1 of the Social Security Finance Bill.

JUNE TO SEPTEMBER

The *Commission des comptes de la Sécurité sociale*, (Social Security Accounts Committee), chaired by the Minister in charge of Social Security, analyses the Social Security system accounts twice a year (in June and September) and publishes two baseline reports on the state of its finances.

The *MECSS* (*Mission d'évaluation et de contrôle de la Sécurité sociale - Evaluation and Monitoring Mission on Social Security Finance Acts*), — a body reporting to both chambers of Parliament — is the designated body with organic responsibility for LFSS monitoring and inspection.

The National Assembly also evaluates the proper implementation of the text by organising the *Printemps social de l'évaluation* (Spring Social Security Evaluation) in parallel with the *Printemps de l'évaluation pour les lois de finances* (Finance Act Spring Evaluation).

DECEMBER

MARCH

THE NATIONAL ASSEMBLY /
SENATE DEBATE

THE
PLFSS
VOTE

CONSTITUTIONAL
COUNCIL

OJ

(OFFICIAL
JOURNAL
OF LAW)

5• Why is this law voted on by Parliament every year?

Like all other finance legislation, the LFSS is, in principle, reliant on **an annual budget to ensure that public spending can be reviewed on a regular basis and controlled as best as possible**.

However, the need for a multi-year overview in addition to the annual budgeting exercise is increasingly recognised by all those involved. The organic law of 14 March 2022 relative to the LFSS also provides for the inclusion in Appendix B to the PLFSS of a “*compteur des écarts*” (deviation meter) to compare the expenditure as forecast in the Public Finance Programming Act (LPPF) with the expenditure targets set out in the finance bills. Under certain circumstances, the Government must justify these deviations, and explain the measures it intends to introduce to educe them.

N.B.: Following the first application of this organic law in relation to 2022, it seems unlikely that the level of detail produced by this ‘deviation meter’ will provide adequate monitoring of funding for medicines.

6• How do medicines fit into the LFSS?

Medicines are not covered by a specific consolidated Social Security budget, but are included in a number of Ondam (► see Question 7) expenditure sub-targets: outpatient care and inpatient care, which do not make it easy to understand the savings measures the industry is required to implement.

From the pharmaceutical company perspective, the LFSS is a channel for dialogue with the legislator. It is the only opportunity for public discussion of medicines policy in France. This is a reductive perspective, since respecting the scope of the LFSS means that it may be discussed only in financial terms, where the emphasis is inevitably on savings. Any overview of the challenges facing the industry that could inform the decisions made by Members of Parliament is unfortunately absent from these discussions, due to the lack of a suitable legislative channel and time constraints.

Nevertheless, the LFSS is quite clearly a structurally important parameter governing the overall dynamics of the French medicines market. (► see *Fact Sheet 1, Medicines: a regulated economy*).

7• Focus on the Ondam

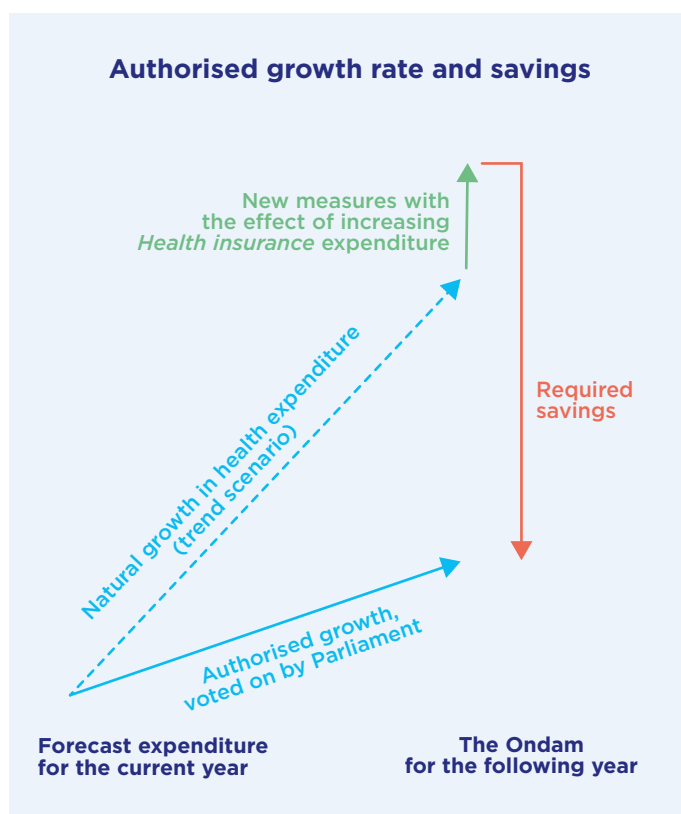
Unlike the Finance Act, which allocates a budgetary envelope specific to each public policy, the Ondam is effectively a social welfare expenditure target that must not be exceeded.

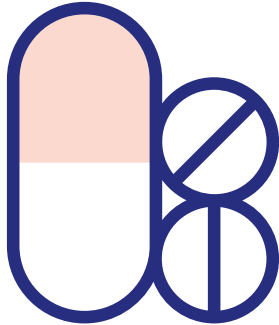
It comprises **6 centres of expenditure** or “sub-targets”), the majority of which refer to the remit of the *National health insurance* scheme:

1. **outpatient expenditure**, including one part of expenditure on medicines;
2. **expenditure on healthcare facilities**, including the other part of expenditure on medicines;
3. expenditure on care and services for the elderly;
4. expenditure on care and services for people with disabilities;
5. expenditure on the regional action fund;
6. other care-related centres of expenditure.

The Ondam is prepared using a number of indicators (► see Question 8).

The *National health insurance* expenditure target (Ondam)





9• Why is there a discrepancy between the law and the reality of the healthcare system?

Pharmaceutical companies identify **two types of discrepancy**:

- a discrepancy between the forecast for the current year and the actual data for the current year;
- a discrepancy between the trend acceptable to the authorities and the trend in actual volumes used to treat patients.

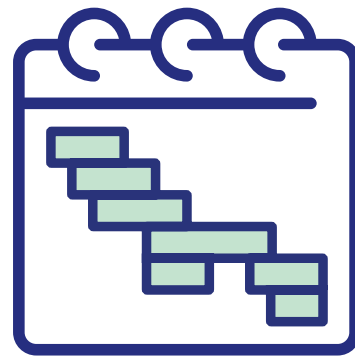
8• To what extent is the LFSS a channel for pharmaceutical regulation?

The LFSS is a structural element of the French reimbursed medicines market, because it defines the level of growth “acceptable” to the State in respect of expenditure on medicines, the overall level of savings required and the measures needed to deliver that level of savings.

Medicines make the largest contribution to healthcare system savings: in 2023, the regulatory measures imposed on medicines will contribute more than €3 billion as a result of the Ondam (► *see Fact Sheet 2, The four levers of medicines regulation*).

A certain level of savings must be achieved in order to avoid exceeding the level of expenditure set by the Ondam. This is a **4-stage process**:

1. Decision on the level of authorised growth in expenditure on medicines.
2. Calculation of the natural growth in expenditure if no additional action is taken.
3. Estimated costs of the new measures required (implemented the following year).
4. Calculation of the savings required to achieve the Ondam level for the following year.



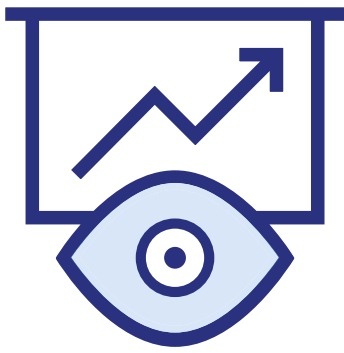
UPSTREAM

→ The timeframe issue

The PLFSS forms the basis for decision-making about the following year, despite the fact that the current year has yet to end; the DSS works on a number of forecasts whose reliability varies, because they are made in July of the current year (► *see the PLFSS timeframe in the answer to Question 4*).

The absence of consolidated publicly available indicators shared with the industry makes this a rather hazardous process when it comes to medicines.

Social Security accounts are only actually recorded in March/April of the following year. But even when the real data are known, the major balances of the social security budget allocations are not revised accordingly. The pharmaceutical companies deplore this state of affairs. The annual nature of the budget makes it impossible to achieve the detached perspective required to build a strategy for medicines that would allow the level of pressure imposed to be aligned with actual expenditure.



DOWNSTREAM

→ Accounting perspective versus regulatory perspective

The difference between these two perspectives can be summarised in **two questions**:

1. **The accounting perspective:** how much did the *National health insurance* actually spend on medicines compared with forecast?
2. **The regulatory perspective:** have the savings measures sufficiently slowed the spontaneous growth in sales of reimbursable medicines? Is this economic pressure sustainable for the industry?

At no point in the PLFSS process is the overarching accounting perspective of Social Security expenditure and savings reconciled with the regulation of medicines. Neither is there any dialogue whatsoever between the industry and the public authorities on this issue. The only information shared publicly is that relating to individual regulatory levers: **the *Comité économique des produits de santé* or CEPS (healthcare products pricing committee)** annual report simply quantifies the savings made through price cuts and clawback payments. An estimate of savings made as a result of medical cost containment through prescription control is included in **the social security policy evaluation report** (► *Appendix 1 to the LFSS*).

The CCSS (Social Security Accounts Committee) reports published in June and September each year provide some of the information required to reconcile these two perspectives, but without drawing any explicit conclusions.

This dichotomy prevents LFSS stakeholders from gaining a meaningful overview of the impact their decisions have: they may be under the impression that they are sending strong growth signals to the industry, when these are actually eroded as a result of accountancy, or conversely that provisions they perceived as harmless may have harsh consequences for the pharmaceutical industry.

For several years now, there has been a widening gap between the accounting budget for medicines — which triggers the safeguard clause — and the actual budget that contributes to reimbursements made by the *National health insurance* scheme. In reality, the total amount represented by this gap constitutes a financial impasse.



DOWNSTREAM

→ Overspending and underspending

Overspending means expenditure is higher than the level forecast in the social security accounts. Conversely, underspending means that expenditure is lower.

So making excessive savings results in underspending, and vice versa.

Overspending can be the result either of insufficient savings (less is saved, so more is spent) or a level of consumption higher than forecast (demand for reimbursed medicines is higher than expected, so more is spent, even if all the savings initially planned were actually made).

- **Successive LFSSs have increased the role of price cuts and clawback payments to the point where they now constitute the main levers for making medicines-related savings.**
- **Medical cost containment through prescription control measures (► see *Fact Sheet 2, The four levers of medicines regulation*) have been underspent by almost 50% relative to target for the last two financial years reviewed. Designed to maximise the relevance of care prescribed, it would be beneficial if these measures were revitalised for future years.**

10• Why is rebasing necessary?

Rebasing refers to the retrospective adjustment applied to the multi-year expenditure trajectory set previously by the Government as part of the LFSS to reflect actual data.

This in-year adjustment mechanism avoids the pitfall of forecasts being carried forward from year to year, and therefore prevents financial deficits from being carried forward year on year. The result is the ability to retain the spirit of governmental decisions (e.g. increasing the budget for medicines), at the same time as preventing any off-target drift resulting from inaccurate forecasts.

Developing medicines regulation has traditionally (and legally until 2019) been based on two factors:

- **a baseline level of pharmaceutical sales**, reflecting market conditions at the time the LFSS is voted on in Parliament, and is therefore a projected budget (▶ *see the answer to Question 9 above*);
- **a rate of growth acceptable to the National health insurance**, that reflects additional spending requirements for the coming year, and which are usually the subject of public announcements.

Deviations from the forecast baseline (excessive levels of savings identified too late, accounting changes for the year in question, underestimated market dynamics, etc.) have resulted in the authorisation of excessively low expenditure thresholds being set for the following year. This has been the case for several years now. So the decision taken regarding the regulation of medicines within the LFSS has failed to meet growth needs and to achieve the targets set. In a few rare instances, it has proved possible to make a retrospective correction in the following LFSS (as was the case in 2019).

The proposal from pharmaceutical companies is to make the method for calculating the regulatory mechanism - which forms the baseline to which the growth rate is applied — explicitly clear, and to link it to a corrective mechanism applied during the year, because the baseline is necessarily a projected budget at the time of LFSS development.

The regulatory mechanism for the current year would then be adjusted as and when necessary if the actual (previous year) baseline were to diverge from the forecast made at the time the LFSS was developed. The growth targets set could therefore be fully implemented to meet the growing demand and need for medicines.

CASE STUDY

Analysis of the 2019 medicines regulation

2019 provides a textbook case illustrating many of the issues raised in this practical guide on medicines in the context of the LFSS.

It all began in summer 2018 at the Strategic Council for the Healthcare Industries (CSIS), the discussion and political decision-making forum that brings public authorities together with healthcare industry stakeholders, including representatives of the pharmaceutical industry.

It was at this event that the then Prime Minister Edouard Philippe announced the following plan for pharmaceutical industry forward visibility: *«a minimum annual growth rate of 3% for innovative medicines and 0.5% for revenue, equating to 1% of reimbursed expenditure for all medicines over three years».*

The then brand-new “*enveloppe M*” was set by allocating 0.5% growth to estimated net revenue for 2018, less the safeguard clause.

$$\text{Enveloppe M for 2019} = 1.005 \times [(\text{Net sales for 2018}) - (\text{estimated safeguard clause repayment})]$$

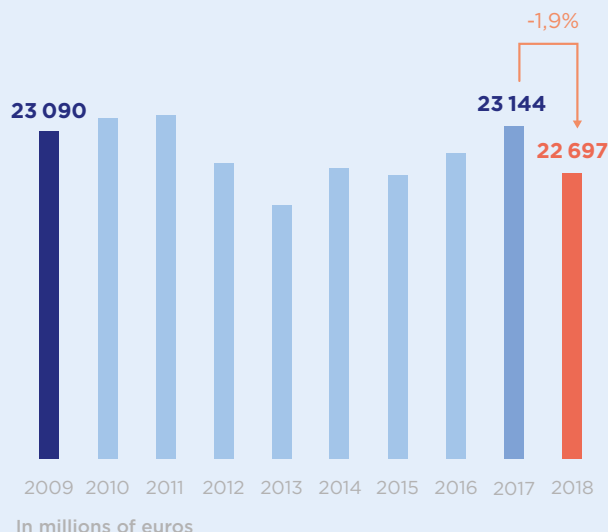
At the end of the 2018 accounting period, the outcome was uncontested: excessive savings were made in 2018, and despite higher than expected natural market growth, net revenue was well below forecast.

- **Price cuts: + €125m in savings** (€995m actual, compared with the €870m forecast).
- **Clawback payments: + €340m in savings** (€552m more in additional clawback payments received than in 2017, rather than the €210m forecast).

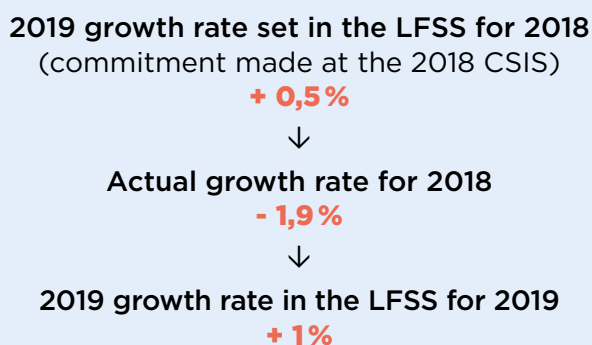
→ **Underspending on medicines: - €435m (as reported by the French Social Security Accounts Committee).**

The baseline effect therefore produced a very unfavourable outcome: at the level of growth previously announced (+0.5%), the discrepancy between the actual figures for 2018 and the estimates made the previous summer had resulted in a 2019 *Enveloppe M* that was actually lower than the net revenue generated by the industry in 2017; an outcome very different from the commitments to forward visibility and growth made by the Prime Minister.

REVENUE GENERATED BY MEDICINES REIMBURSED BY THE NATIONAL HEALTH INSURANCE (dispensed by hospital and community pharmacies), **NET OF ALL REPAYMENTS** (product clawback payments, ATUs (temporary authorisations for use) and the safeguard clause)



The industry therefore requested an increase in the authorised growth rate, and received the President’s undertaking that this growth rate would be increased to 1% in the PLFSS for 2020 to partially offset the effect of over-regulation in 2018.



But the misfortunes of 2019 continued... At the end of the 2019 accounting period in spring 2020, the Court of Audit in its general social security system accounts certification report drew attention to an accounting transaction that had effectively delayed €700 million in clawback payments made by the industry being taken into account until the following year, triggering a repayment by the industry under the terms of the safeguard clause.

The June 2020 report of the French Social Security Accounts Committee then noted that the actual expenditure on medicines by the *National health insurance* in 2019 again fell far below the forecast accounts used when preparing the Ondam:

- **Price cuts: + €230m in savings** (€1,191m actual, compared with the €960m forecast)
 - **Clawback payments: + €130m in savings** (€330m more in additional clawback payments than in 2018, compared with the €200m forecast). **This excessive level of savings would rise even further to €900 million were the ‘delayed’ clawback payments to be reallocated.**
- **Underspending on medicines: - €260m** (as reported by the French Social Security Accounts Committee).

IN CONCLUSION

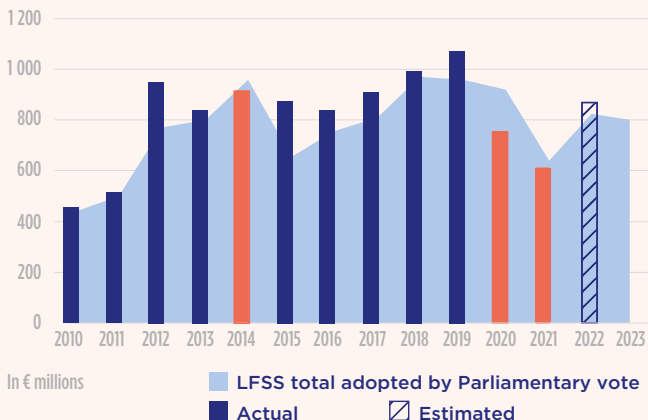
- In 2019, a ‘baseline effect’ driven by excessive implementation of the 2018 regulatory mechanism in combination with an accounting transaction led to the industry paying €159 million in growth-related tax, despite the fact that the *National health insurance* had spent €260 million less than forecast on medicines.
- It was only this accounting transaction that made it possible to meet the President’s commitment to 1% growth in 2019.

ADOPTED VERSUS ACTUAL

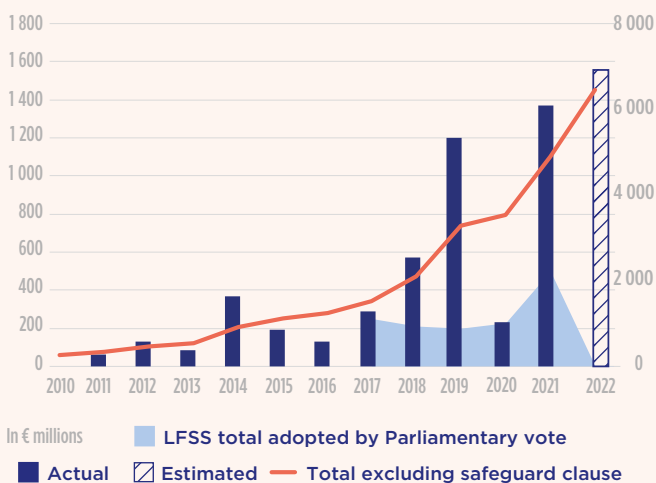
For more than a decade, there has been a discrepancy between the amounts adopted by Parliament when voting on the LFSS and the reality experienced by pharmaceutical companies in the following year. The lack of transparency in the legal text submitted to Parliament means that the LFSS vote is becoming increa-

singly meaningless. Leem calls for savings made in recent years as a result of price cuts and annual clawback payments made by manufacturers have almost always been excessive, whereas savings as a result of medical cost containment through prescription control (the relevance of prescriptions) have been significantly under-applied. In parallel with these savings measures, the safeguard clause has been triggered almost every year since 2014 (see pages 19-20). The bottom line is that pharmaceutical company net sales growth remained at zero between 2010 and 2019. Although the industry returned to moderate growth in 2021, the available regulatory tools are now being pushed to their limit, raising serious questions about the long-term future of pharmaceutical companies and the attractiveness of France for the pharmaceutical industry.

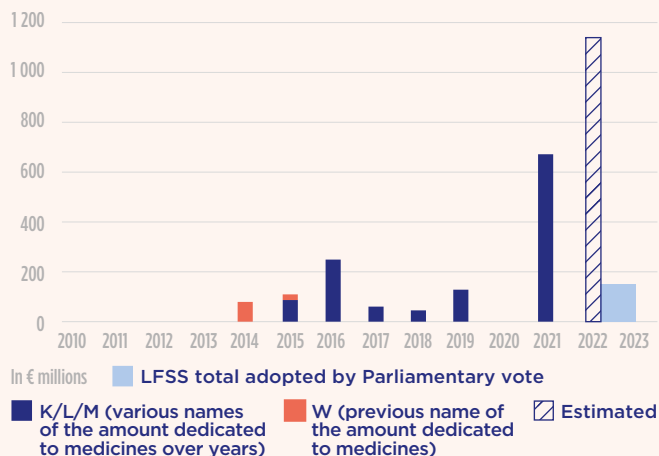
Excessive price cuts



Exponential growth in clawback payments

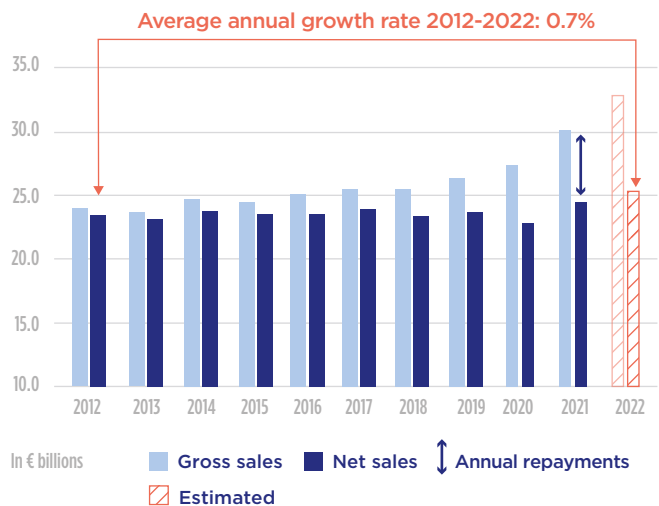
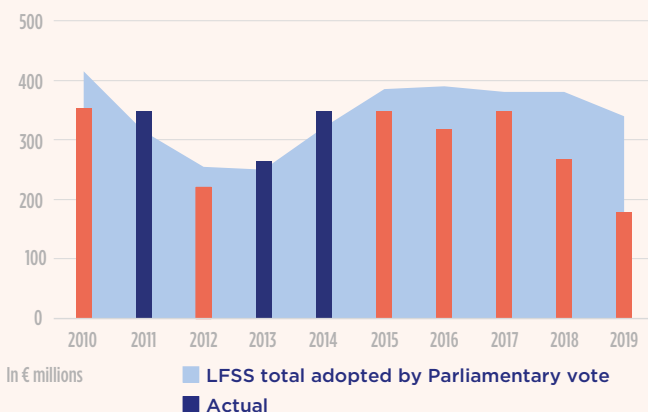


Systematic triggering of the safeguard clause



Gross sales versus Net sales

Relevance of prescriptions: a source of savings to be revitalised



MEDICINES: A REGULATED ECONOMY (2012-2022)

DEFINITIONS

The term ‘regulated net revenue from medicines’ refers to industry turnover generated from sales of all medicines eligible for reimbursement by the *National health insurance*, as regulated in the *Ondam National health insurance* expenditure target for medicines dispensed by community and hospital pharmacies, minus the contractual or mandatory clawback pay-

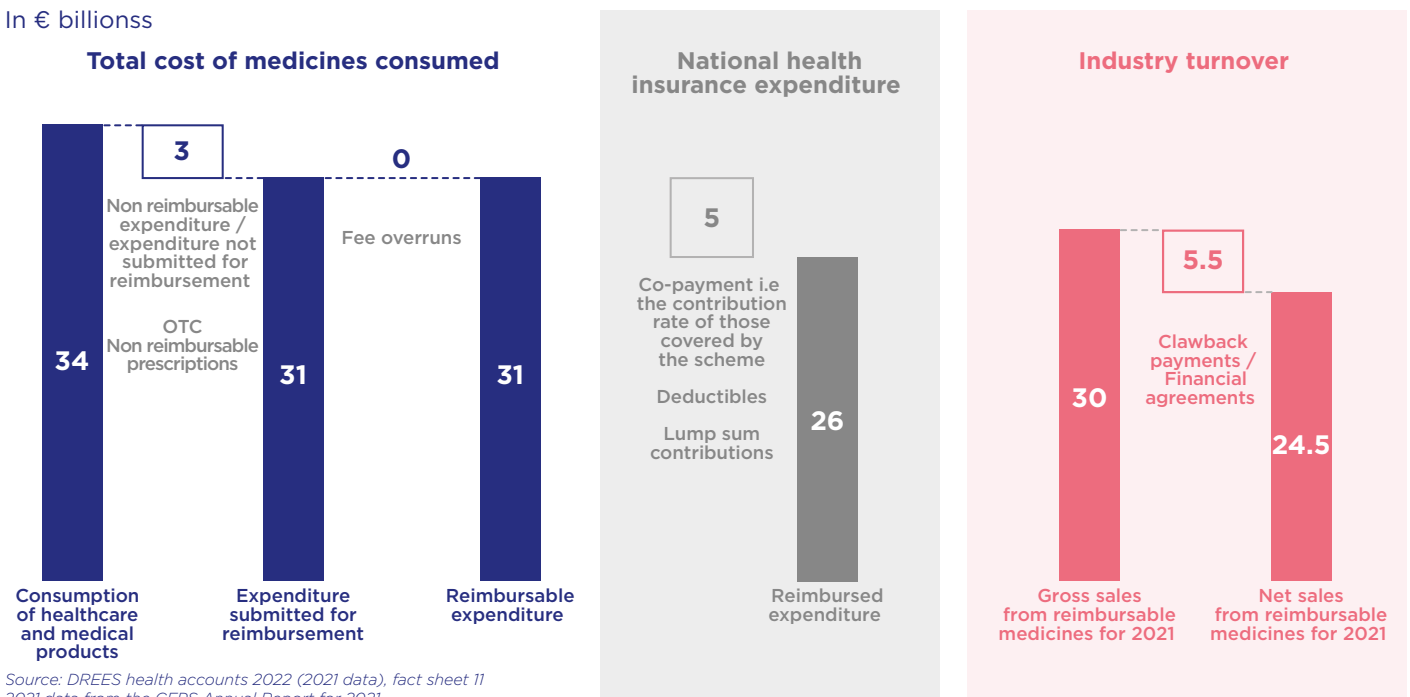
ments made by the industry (► see *Fact Sheet 2, The four levers of medicines regulation*).

The total level of regulated net revenue above which the industry must repay a proportion of the surplus to the *National health insurance* is referred to as “**contribution M**” or the “**safeguard clause**”.

NATIONAL HEALTH INSURANCE EXPENDITURE OR INDUSTRY REVENUE: TWO PARALLEL PERSPECTIVES

The example of 2021

In € billions



Source: DREES health accounts 2022 (2021 data), fact sheet 11 2021 data from the CEPS Annual Report for 2021

TREND IN NET REVENUE FROM SALES OF MEDICINES

The trend in net revenue from sales of medicines in recent years can be broken down into **three periods**:

2010 – 2019 :

A DECADE OF HYPER-REGULATION

	2010	...	2018	2019
Revenue from sales of regulated pharmaceuticals at PFHT (pre-tax manufacturer price) net of clawback payments and safeguard clause (€m)	23 800		23 365	23 749
Residual net growth over the period			-0.2%	

Over the last decade, regulation has reduced growth in net turnover from sales of regulated medicines to 0%. This level of hyper-regulation can be seen as

paradoxical in light of demographic change, population ageing, disease chronicity and sequential waves of innovation in treatments.

2019 – 2021 :

A MARKET IMPACTED BY COVID AND CREATIVE ACCOUNTING

	2019	2020	2021
Revenue from sales of regulated pharmaceuticals at PFHT (ex-manufacturer price) net of clawback payments and safeguard clause (€m)	23 749	22 880	24 481
Residual annual growth	+1.6%	-3.7%	+7.0%

Pharmaceutical market growth fluctuated between 2019 and 2021. However, this trend should be seen in the context of the Covid pandemic, which had a major impact on drug consumption in 2020, and the

carry forward to 2020 of clawback payments relating to 2019 (which artificially increased turnover for 2019 and reduced turnover for 2020, thereby artificially inflating the growth figure for 2021).

2021 – 2023 :

A DYNAMIC MARKET SQUEEZED BETWEEN INFLATION AND REGULATION

	2022	2023
Revenue net of clawback payments and safeguard clause (€m)	25 347	25 947
Residual annual growth	+3.5%	+2.4%

The pharmaceutical market has been particularly dynamic since 2021. Growth in gross revenue from sales of medicines (before clawback payments and safeguard clause) tripled from 3% at the end of 2010 to approaching 10% in 2022. The majority of this growth has been driven by the market launch of new medicines and new indications. Net market growth

remains positive, despite the exponential rise in clawback payments (1.6 times forecast between 2021 and 2023) and the effects of the safeguard clause (2.9 times forecast), flagging up the significant economic pressure on the industry as a whole. It is important to note that this level of growth is still below inflation for the same period (5.2% in 2022).

FOCUS

THE PROPORTION OF THE ONDAM REPRESENTED BY MEDICINES

Health expenditure within the Ondam scope rose by an average of 3.1% between 2010 and 2022. In mechanical terms, the ratio between net revenue from sales of medicines and Ondam expenditure decreased year on year during this period. From 11.6% in 2012, it had fallen to 9.1% in 2022.

<i>(In € billions and in percentage)</i>	2010	2015	2021	2022 (estimated)
Net revenue from sales of regulated pharmaceuticals at PFHT (ex-manufacturer price), reimbursed under the basic health insurance schemes	18.91	19.28	20.77	21.29
Ondam expenditure (excluding Covid expenditure between 2020 and 2022)	161.9	181.8	221.8	234.9
Proportion of the Ondam represented by medicines at PFHT (ex-manufacturer price)	11.68%	10.61%	9.36%	9.06%



THE FOUR LEVERS OF MEDICINES REGULATION

MEDICINES ARE THE MAIN CONTRIBUTORS TO THE SAVINGS MEASURES INCLUDED IN THE LFSS

In 2023, the LFSS determined that the total revenue generated from sales of regulated medicines should contribute 9.1% of the Ondam, excluding Covid-19 and *Ségur de la santé* healthcare reform measures* (► see *Fact Sheet 1, Medicines: a regulated economy*).

However, the contribution actually made by the industry as a result of regulatory measures is significantly higher, with medicines alone contributing more than €3 billion of the savings earmarked at the time of Ondam preparation.

**The Social Security deficit is likely to fall to €8.2bn in 2023, as a result of continued revenue growth and the fall in expenditure post-Covid. However, the Social Security deficit is expected to worsen further from 2024 onwards, despite the expected favourable effects of pension reforms:*

- *The deficit balance of the old-age section of the general Social Security system and the old-age welfare fund will be €4bn in 2030.*
- *The Caisse nationale de retraite des agents de la fonction publique locale et hospitalière (CNRACL - the national retirement fund for civil servants and hospital staff) will be more than €6bn in deficit in 2030 déficit de plus de 6 Md€ en 2030.*

IMPLEMENTATION OF SAVINGS ON MEDICINES

Medicines are regularly the focus for specific savings-related reforms and measures: for example, changes to the rules on the reimbursement of generics, the introduction of in-pharmacy substitution for biosimilars and hybrid medicines, and changes to the terms of the 'Contribution M' (see *the Focus pages 19 to 22*).

In addition to these specific measures, **four levers are used every year to regulate medicine expenditure** as part of preparing the Ondam (see *the following page for the relevant graphs*).

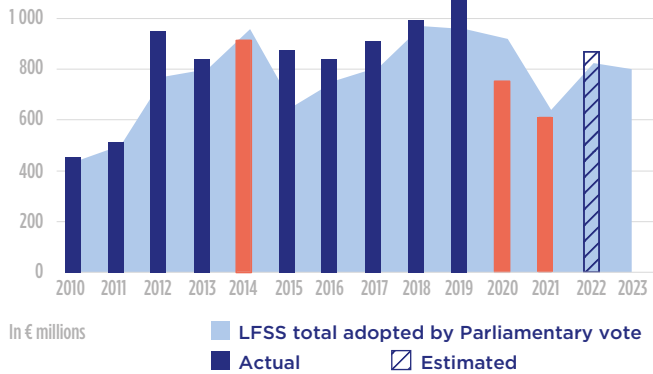
The safeguard clause is applied retrospectively to regulate pharmaceutical industry revenue. It is used to "make up" for any under-application of the other regulatory levers detailed on page 18.

It would be a mistake to consider these levers as independent of each other: for example, reducing the savings targets for price cuts without increasing the *Montant M* would effectively ease the regulatory pressure on companies imposed by price cuts, but automatically increase the overall amount of the safeguard clause. **The entire system is interconnected.**

Leem will be paying particularly close attention to the total amounts of medicines-related savings imposed by the PLFSS for 2024. Simply transferring savings between price cuts and the safeguard clause will not deliver a satisfactory response to the regulatory pressure to which companies are currently subject.

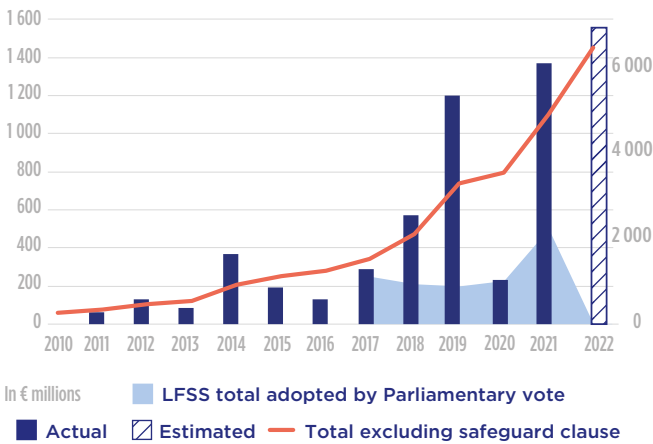
The four levers used to regulate expenditure on medicines

1. PRICE CUTS



Price cuts agreed between the French Healthcare Products Pricing Committee (CEPS) and those companies marketing reimbursable medicines in France.

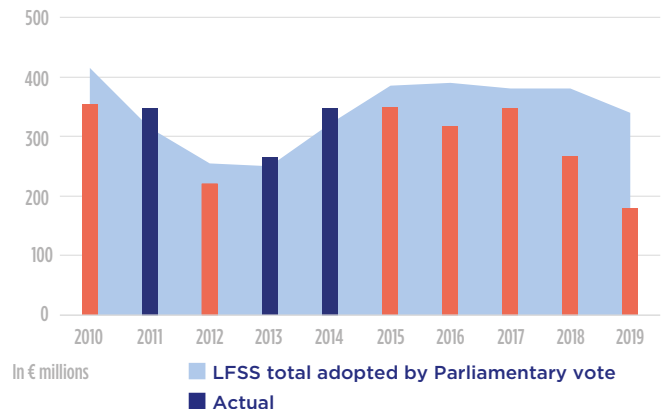
2. CLAWBACK PAYMENTS



Clawback payments, enable the *National health insurance* to pay a lower price than the standard retail price for certain medicines. These payments are made annually by the manufacturers concerned. The amount of these payments and the medicines they relate to are agreed between the CEPS and the pharmaceutical companies (4.5% of listed products are subject to a negotiated price), but in some specific cases (e.g. early access products), they are set by law.

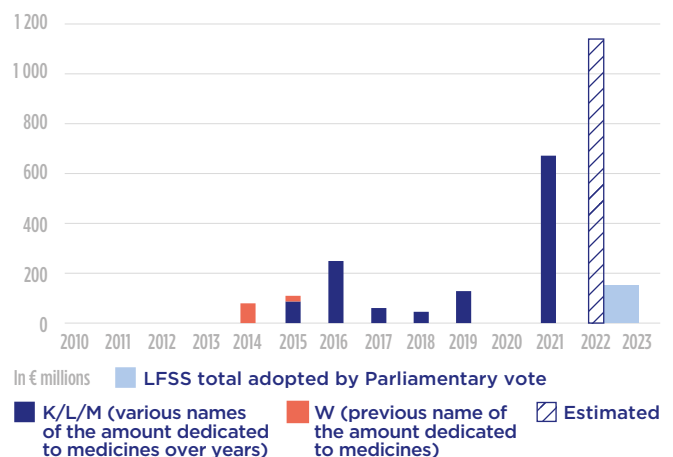
From 2022 onwards, clawback payments have no longer been included in the total savings shown in Appendix 5 to the PLFSS, but are now included directly when developing the trend scenarios, further reducing transparency around the medicines-related data used in preparing the Ondam.

3. RELEVANCE OF PRESCRIPTIONS CONTROL



Medical cost containment through prescription control refers to actions implemented by the *National health insurance* with the aim of improving the relevance of prescription and medicine consumption. During the Covid pandemic, CNAM ceased monitoring this indicator. The latest available data relate to the 2019 financial year, and it is our view that medical cost containment through prescription control should once again be closely monitored going forward.

4. SAFEGUARD CLAUSE



The safeguard clause is triggered when net revenue generated by medicine sales exceeds the *Montant M* adopted as part of the Parliamentary vote on the LFSS.

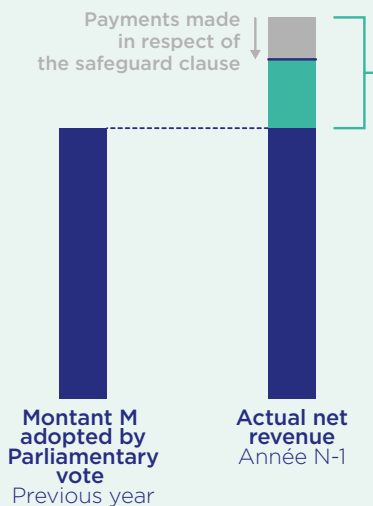
FOCUS

THE SAFEGUARD CLAUSE

Contribution M, —also known as the ‘**safe-guard clause**’ (CS)— is a contribution payable by companies exploiting one or more medicines when the revenue generated by one or more proprietary pharmaceutical products —excluding tax and net of clawback payments— in mainland France and the overseas departments exceeds the preset “*Montant M*” threshold.

The safeguard clause is governed by Articles L. 138 and subsequent of the French Social Security Code. This threshold is set annually in the **Social Security Finance Act (LFSS)**. Historically, it took the form of a permitted rate of growth relative to pre-tax revenue for the previous year. Since the LFSS for 2021, it has been a fixed amount adopted by Parliamentary vote.

How does the safeguard clause work?



What?
Revenue generated by sales
(in mainland France
+ its overseas departments)
of regulated medicines net
of clawback payments



Manufacturers return a proportion of the revenue generated over and above the fixed amount set by the LFSS on the basis of a progressive scale:

< M + 0.5%	50% of the excess
M + 0.5% → M + 1%	60% of the excess
> M + 1%	70% of the excess

HOW THE CONTRIBUTION IS DIVIDED BETWEEN PHARMACEUTICAL COMPANIES

→ **Each company's contribution is calculated individually**
pro-rata revenue generated within the safeguard clause scope.

AMENDMENT INTRODUCED BY THE LFSS FOR 2023:
70% pro-rata revenue and 30% pro-rata company growth. The aim of this amendment is to limit the impact of the safeguard clause on companies experiencing slow growth or decline.

→ **Each pharmaceutical company enters into an individual contract**

A reduction of between 5% and 20%, depending on the contribution made to savings by pharmaceutical companies agreeing price cuts.

→ **Individual cap**

10% of company gross revenue.

A measure introduced by the LFSS for 2023 amended this cap on a transitional basis.

For 2023, this is set at 10% of net revenue for consistency with the safeguard clause scope; a change that the industry would like to see made permanent.

How is *Montant M* calculated?

Between 2015 and 2020, the methodology used to calculate the safeguard clause trigger threshold was enshrined in law. Although this description has not appeared in the legislation since 2021, Government has followed the historical method when setting the trigger thresholds for 2021 and 2022.

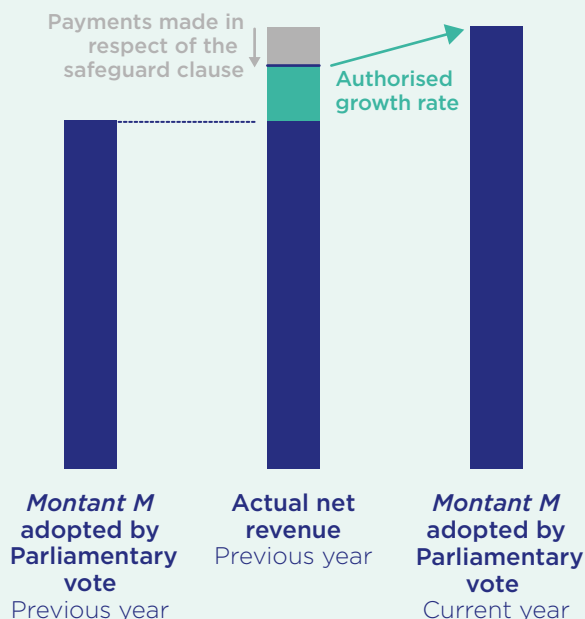
So ever since 2015, the rule used to calculate the total medicines-related revenue above which the safeguard clause is triggered for the current year has been based on the previous year's revenue minus the amount due under the safeguard clause for that year.

This method can be summarised in the following formula:

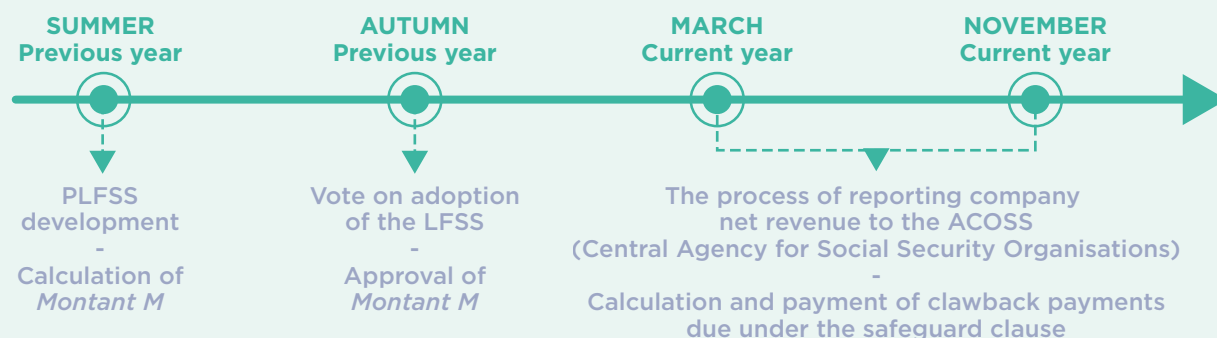
$$\text{Montant M} = (\text{net pharmaceutical industry revenue for the previous year} - \text{safeguard clause}) \times \text{growth rate}$$

This rebasing method (> see Question 10 p.11) makes it possible to link the safeguard clause trigger threshold to market trends, which are nothing more than a reflection of public needs.

The methodology used to calculate *Montant M* for 20s23, which is virtually identical to that for 2022 (+0.4%), has not been publicly disclosed, but marks a clear break with the method previously used (see page 22).



From the setting of *Montant M* to clawback payments made by manufacturers



In recent years, the final amount of the contribution has not been notified until Quarter 4 of the following year, and the contribution for 2021 was notified as late as January 2023.

The 2023 LFSS redefines the legal timetable, and stipulates that the entire process must now be completed by 1 November of the following year.

As a result, the pharmaceutical industry net revenue figure for the previous year remains unknown at the time the PLFSS is developed, and even at the end of the Social Security accounting period; a state of affairs strongly criticised by the Court of Audit in its certification report on the Social Security accounts for 2022.

The safeguard clause: a regulatory tool in the process of being hijacked

When first introduced, the safeguard clause was intended to be just that: a safeguard against an unexpected increase in expenditure on medicines. But since 2014, it has led to virtually systematic payments by the industry as a direct result of a gap between the situation the regulator wants and the reality of dynamic natural growth in need. The estimate shared in the May 2023 report published by the French Social Security Accounts Commission forecasts safeguard clause payments to be in the region of €1.1bn for 2022, an even higher amount than the €680m seen in 2021, which was itself nearly 3 times the previous historic high. This level of payment could double between 2022 and 2023.

A target for the revenue generated by the safeguard clause has been included in the appendices to the PLFSS since 2022; a move that totally contradicts the “safeguarding” principle. It seems likely that this target – €150 million for 2023 – will be significantly exceeded. The safeguard clause is therefore now a fully-fledged instrument for regulating expenditure.

Furthermore, the report of the expert panel set up to review the system for financing and regulating health products (see page 37) recommends a forward trajectory of reducing the safeguard clause to bring its total effect below €500m.

Unpredictability harms companies

Initial estimates of the amounts to be paid by pharmaceutical companies as a result of the safeguard clause are based on an estimate of the total net revenue generated in the current year by all companies operating in the regulated medicines market. This estimate is usually prepared on the basis of the previous year's data.

Multiple uncertainties explain the difficulties experienced by companies in putting a value on this figure:

- the current year net revenue figure for the industry is not accurately known until midway through the following year;
- the clawback payment totals are not known until the end of the following year;
- the amounts relating to regulatory mechanisms remain unknown until publication: at the end of the following year for price cuts, and at the end of the year after that for medical cost containment through prescription control.

As discussions around the PLFSS for 2022 have highlighted, the same difficulties are experienced by Government. An amount of €400 million as a result of the safeguard clause for 2021 had originally been suggested by Government. However, the amount ultimately paid by companies in January 2023 turned out to be almost twice that of the initial estimates.

These discrepancies between estimates and actual data have direct consequences for pharmaceutical companies:

- an uncertain situation that challenges the understanding of parent companies and auditors, and undermines the attractiveness of basing subsidiary companies in France;
- an impact on budget management and the achievement of company targets; these retrospective changes may, for example, result in companies having to revise their financial statements for the previous year.

2023: the year of U-turn

Medicines regulation was the subject of intense debate during consideration of the PLFSS for 2023. *Montant M* has been set at €24.6bn, reflecting a 0.4% increase on the *Montant M* of €24.5bn for 2022. Leem disagrees with the Government over the basis used to calculate the safeguard clause.

On the basis of work carried out by the Strategic Council for the Healthcare Industries (at the 2021 CSIS), the President committed to a healthcare product growth rate of 2.4% over a three-year period.

At the time of the PLFSS for 2022 – the first PLFSS following implementation of the presidential announcement – the National Assembly general rapporteur on the legislation explained the methods used to calculate *Montant M*. These explanations were then included in the report of the National Assembly Social Affairs Committee.

The basis of calculation was total industry net revenue minus the estimated yield of the safeguard clause for 2021, which is consistent with the calculation method used since 2015.

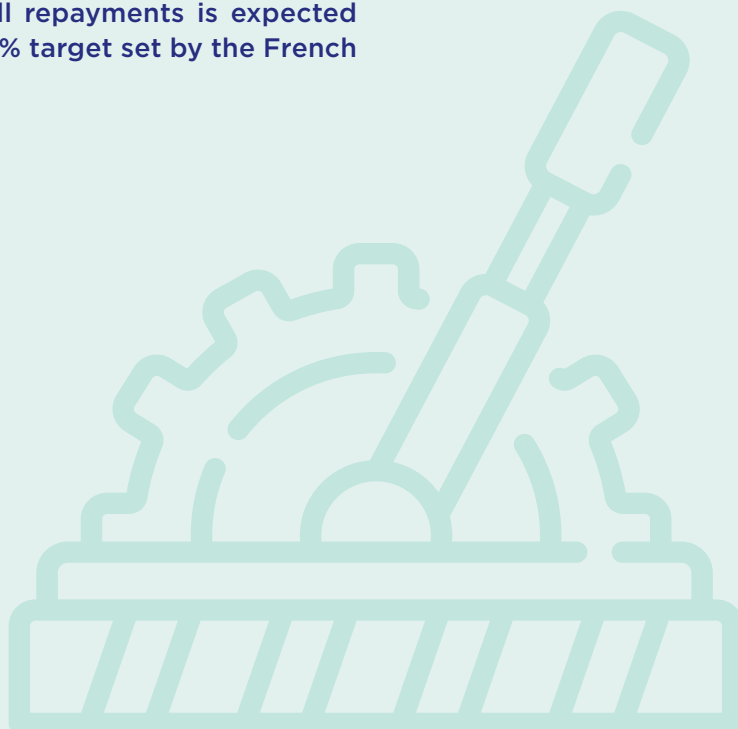
In 2023, the method used to calculate *Montant M* was not disclosed in any speech or official report. In a press release issued at the end of 2022, the DSS indicated that the presidential commitment would be implemented in 2023, since growth in industry revenue net of all repayments is expected to exceed the 2.4% target set by the French President.

Leem contests this line of reasoning, which breaks with the historic methodology used to set *Montant M*. Pharmaceutical market growth, coupled with the subdued trend in *Montant M*, will automatically result in a sharp increase in the safeguard clause. Leem estimates suggest that safeguard clause payments will double between 2022 and 2023.

Leem believes that applying the historic method would have resulted in *Montant M* being €1bn higher than the amount finally approved by parliamentary vote, which would have limited safeguard clause inflation.

The LFSS for 2023 also provides for the inclusion, from 2024, of medicines purchased by Santé Publique France (the national public health agency) within the scope of regulation imposed by the safeguard clause.

This reinstatement will take the clause to a new level of unpredictability, since it covers medicines purchased in response to a health crisis (Covid vaccines, for example), **which are by their nature essential, unpredictable and potentially significant expenses.**



THE PRICE OF MEDICINES IN FRANCE



It is important to remember that the price of a medicine is not set in the LFSS!

WHO SETS THE PRICE OF MEDICINES IN FRANCE?

The French Healthcare Products Pricing Committee (CEPS), which reports to the Ministers in charge of Health, Social Security and the Economy, is required by law to set the prices for those medicines reimbursed by the mandatory *National health insurance* scheme. This mechanism applies to those medicines funded when dispensed by community pharmacies, and two specific categories of hospital-dispensed medicines (those referred to as being “*de la liste en sus*” – invoiceable on top of T2A funding – and medicines sold by hospital pharmacies to outpatients... > see *N.B. opposite*).

Following receipt of recommendations by the National Authority for Health (HAS) Transparency Committee, the CEPS negotiates product prices with those manufacturers wishing to market them. Once negotiations have been completed, this price will be published in the *Journal officiel* (which publishes laws and regulations of the French Republic).

Medicines remain one of the final few sectors of the French economy to be subject to official price controls.

N.B.:

Medicines dispensed in hospitals represent a special case: they are sold at unregulated prices, and their purchase by public healthcare facilities is governed by the public procurement code. There are two exceptions to this freedom of pricing in hospitals, both of which are subject to negotiation and price setting at national level in conjunction with the CEPS:

- *innovative and expensive medicines may be included on a special list, known as the “liste en sus”, which enables them to be funded by the National health insurance outside the scope of activity-based pricing – (T2A);*
- *medicines on the “liste de rétrocession” (medicines that can be sold to outpatients by hospital pharmacies). This dispensing restriction is specific to certain products, for which the hospital pharmacy stands in for the community pharmacy.*

HOW ARE MEDICINE PRICES SET?

There are 3 levels of medicine price negotiation:

1. Legislative

The price setting criteria are set out in Article L162-16-4 of the Social Security Code:

- improvement in actual medical benefit (ASMR)
- comparator country prices
- sales volume
- health economic opinion
- security of supply.

2. Political

Policy guidance is provided to the CEPS in the form of a ministerial policy guidance letter.

3. Conventiennel

A framework agreement between Leem and the CEPS opens up the possibility for agreements that extend beyond purely legal obligations.

Medicines considered innovative by the Transparency Committee may benefit from a 'premium' price relative to those therapeutic solutions already available in the market.

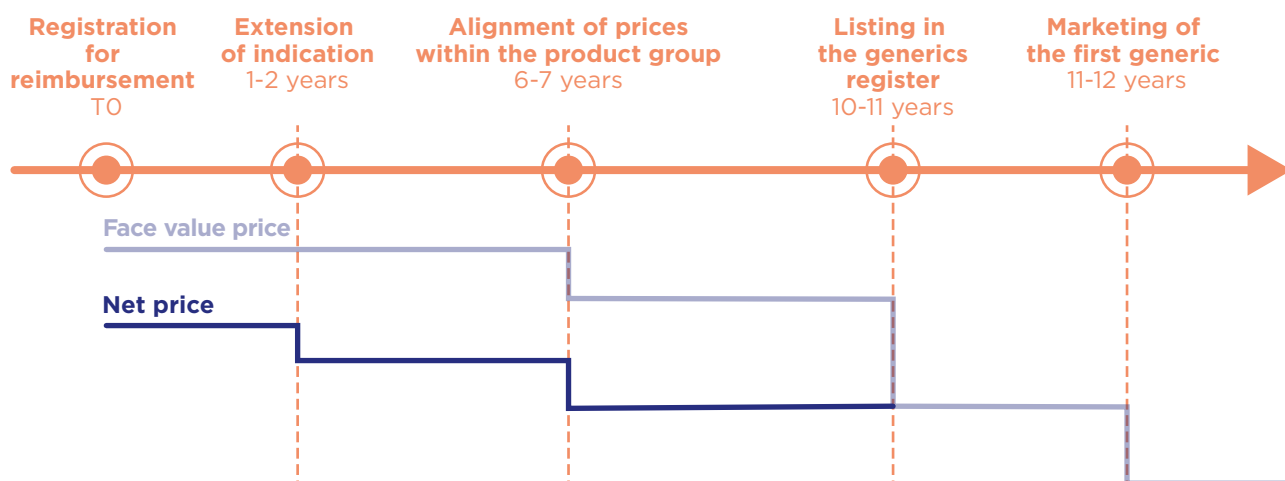
If the medicine concerned delivers no improvement in treatment (no improvement in actual medical benefit or ASMR 5), it must generate savings for the *National health insurance* (R 163-5), i.e. its cost must be lower than that of the therapeutic alternatives.

HOW DO MEDICINE PRICES CHANGE OVER TIME?

Between the time a medicine is first marketed and the point at which its patent expires, the conditions governing its price may change. An extension of indication or reassessment of the product by the Transparency Committee will result in the reopening of negotiations between the CEPS and the manufacturer.

Every year, the CEPS sets the therapeutic groups of products within which price cuts may be requested.

Lastly, when generic or biosimilar medicines enter the market, the price of the proprietary medicine is subject to an initial markdown (of between 20% and 40%, depending on the characteristics of the product), followed by subsequent periodic markdowns related to the market penetration rate achieved by the relevant generics or biosimilars. These different types of markdown are provided for in the framework agreement between Leem and the CEPS.



FOCUS

REIMBURSABLE MEDICINES

Gross versus net price of reimbursable medicines

The Social Security Code (Article L162-18) provides for the possibility of setting the clawback payments associated with certain products by agreement between the CEPS and the pharmaceutical company. The products concerned then are allocated a gross price, which is published in the *Journal officiel*, and a net price that reflects the deduction of

these clawback payments.

These clauses may take the form of agreements based on economic or public health criteria. In 2020, only 4.5% of products priced by the CEPS had an associated clawback payment contract. However, clawback payments are increasingly being used when setting the prices of innovative products.

Reimbursable medicine prices versus pharmaceutical industry's sales

The price set by the CEPS for a reimbursable medicine acts as the baseline for the remuneration received by those stakeholders other than manufacturers involved in its marketing: wholesale distributors and dispensing pharmacists. This remuneration can be broken down into two regulatory mechanisms: margin and clawback payments.

Increasingly, the remuneration received by dispensing pharmacists is being disconnected from medicine prices in order to reduce

the negative impact of price cuts on pharmacy finances: this disconnection is being achieved through the introduction of remuneration based on a dispensing service fee or public health targets. As a result, several types of dispensing fee have been introduced (for medicines specific to certain conditions, age-related, etc.). Dispensing pharmacists can also negotiate the price they pay wholesalers and/or pharmaceutical companies for medicines within the legally regulated range of percentages, which is higher for generics.

PFHT = the pre-tax manufacturer price

The price negotiated between the CEPS and the manufacturer

PGHT = the pre-tax wholesaler price

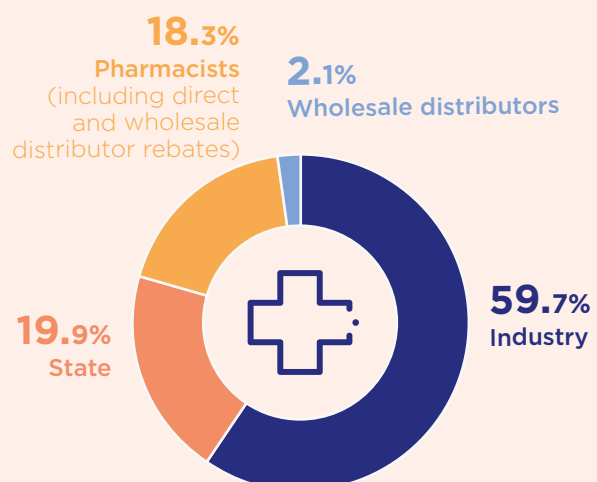
PFHT plus a margin equivalent to 6.93% of the PFHT for remuneration of wholesale distributors, capped at €32

PPHT = Public price excluding VAT

plus a degressive margin equivalent to between 5% and 10% of the PFHT, capped at €97

PPTC = Public price including VAT

plus 2.1% VAT

AVERAGE BREAKDOWN OF VAT-INCLUSIVE REVENUE GENERATED BY REIMBURSABLE MEDICINES SOLD THROUGH COMMUNITY PHARMACIES IN 2021


Who pays for the reimbursement of medicines dispensed through community pharmacies?

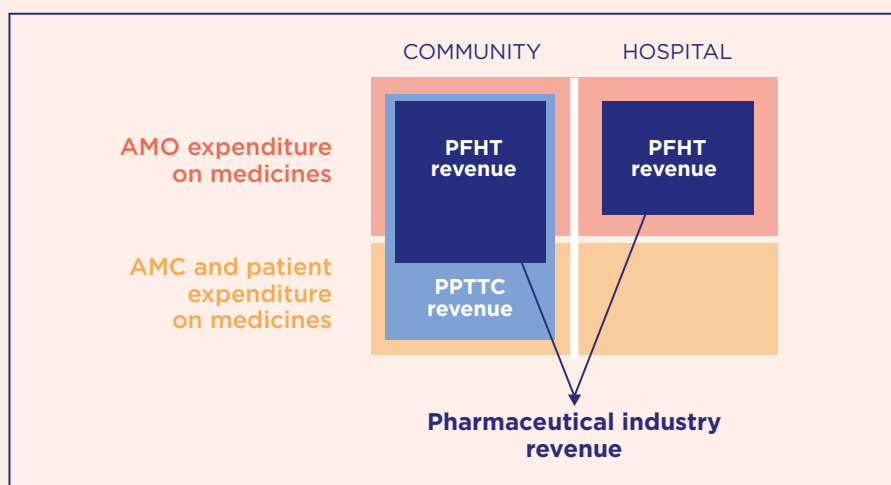
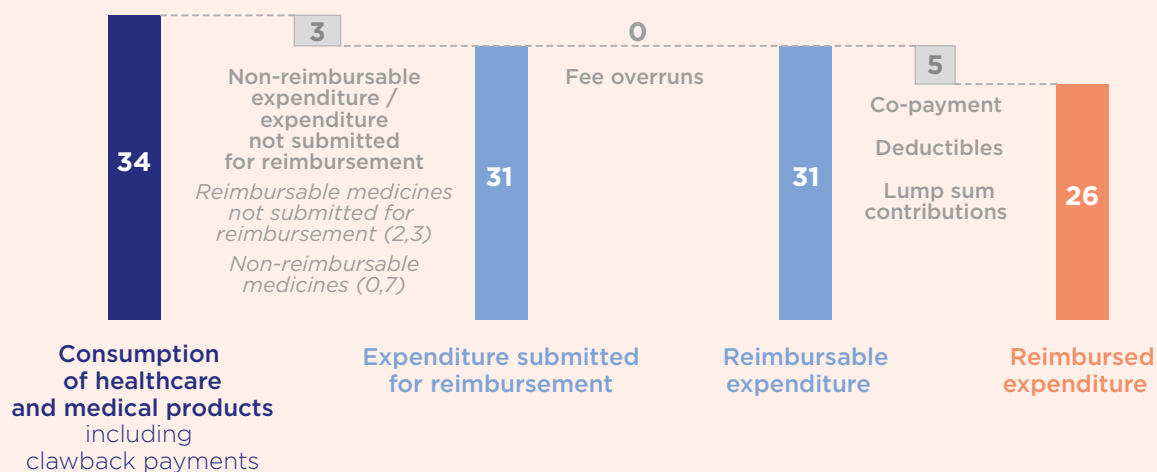
There are currently four reimbursement rates for medicines in the General Social Security Scheme (funded by the Mandatory Health insurance scheme or AMO).

The remainder is paid by Top-up Health insurers (mutuals, provident insurers, general insurers, etc.) – this is referred to as Top-up Health Insurance (*Assurance maladie Complémentaire* or AMC) paid for privately by households.

The four reimbursement rates are:

- 100% for medicines recognised as irreplaceable and particularly expensive;
- 65% for other medicines;
- 30% for medicines intended for the treatment of normally non-serious conditions;
- 15% for certain medicines delivering low levels of Actual Medical Benefit.

**THE FUNDING OF MEDICINES
BY THE NATIONAL HEALTH INSURANCE SCHEME
(IN € BILLIONS)**



Source: DREES health accounts 2022 (2021 data), fact sheet 11

Who reimburses the cost of medicines dispensed through hospital pharmacies?

Hospital-dispensed medicines fall into **two categories**:

1. Those medicines covered by the fees charged for procedures by healthcare facilities, where these have been purchased via a tendering structure and equate to overheads;

2. Those medicines funded via the “*liste en sus*” and those on the “*liste de rétrocession*”, which are priced at national level by the CEPS, and reimbursed directly by the *National health insurance* to healthcare facilities on the basis of the actual cost to them:

→ **Medicines on the “*liste en sus*”** are fully funded by the *National health insurance*, which reimburses hospitals for their purchases;

→ **medicines on the “*liste de rétrocession*”,** dispensed by hospital pharmacies to outpatients are reimbursed in the same way as those dispensed by community pharmacies on the basis of a national price (prescription charge) and reimbursement rate;

In both cases, where direct negotiation with the manufacturer has enabled the hospital to obtain supplies below the public price for these medicines, the *National health insurance* pays the hospital the actual amount of its purchase and adds a “premium” representing a fraction of the difference between that amount and the price set by the CEPS.

This mechanism, known as the “*écart médicament indemnisable*” or EMI (reimbursable medicine price difference compensation) is intended to limit over-reimbursement of hospitals by the *National health insurance*, while encouraging the former to negotiate their own prices for supplies.

Hospitals negotiate independently regardless of whether or not there is a clawback payment agreement in place between the manufacturer and the CEPS.



TAXATION OF MEDICINES IN FRANCE

WHAT TAXES ARE APPLIED TO THE PHARMACEUTICAL INDUSTRY?

With six industry-specific taxes and fees (over and above the general taxation regime), the French pharmaceutical industry is the European Number 1 in terms of taxation:

- contribution based on revenue;
- additional revenue-based contribution;
- contribution based on medicine promotional expenditure;

- taxes on direct sales;
- fees for filing marketing authorisation (MA) applications;
- environmental taxes (especially in respect of EPR*).

** Extended Producer Responsibility*

WHAT ARE THE EFFECTS OF THIS LEVEL OF TAXATION ON PHARMACEUTICAL MANUFACTURING IN FRANCE?

The French tax burden on the pharmaceutical industry runs counter to the fiscal and industrial policies seen in the USA and some close European neighbours, such as the UK.

Leem draws attention to **this tax burden** on pharmaceutical companies operating in France, because it compromises the country's attractiveness in terms of inward investment by the pharmaceutical industry.

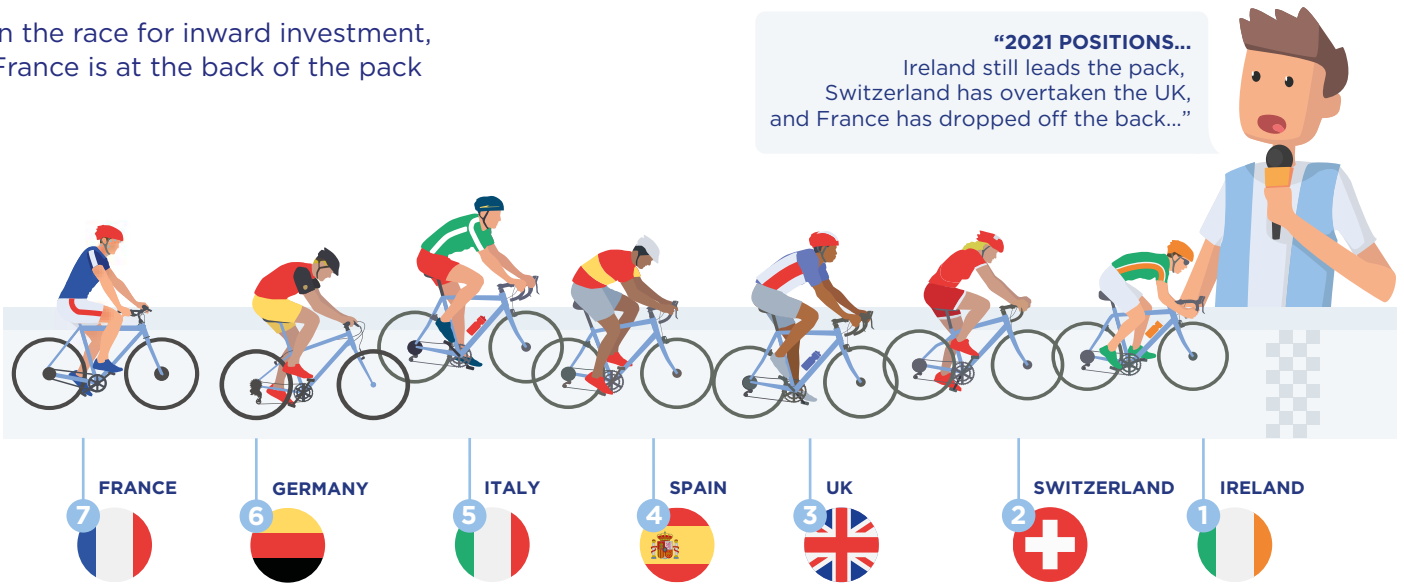
In today's global economy, where taxation is increasingly being used as a competitive weapon by nation states, the excessive level of industry-specific taxes in France is a major handicap at a time when there is such political will to restore manufacturing capacity on French soil to make the country more self-sufficient in terms of healthcare.

In this context, the trend towards using the safeguard clause as an additional industry-specific tax is clearly undesirable (► see *Fact Sheet 2, The four levers of medicines regulation*).

THE TAX TREATMENT OF PHARMACEUTICAL COMPANIES

In the race for inward investment, France is at the back of the pack

"2021 POSITIONS..."
Ireland still leads the pack, Switzerland has overtaken the UK, and France has dropped off the back..."



IMPROVING FRENCH GENERAL TAXATION...



Trend in general taxation between 2019 and 2021	
FRANCE*	OTHER COUNTRIES OF THE STUDY (Spain, Italy, Germany, UK, Switzerland and Ireland)
-14% to -16%	between -1% and +1%

...IN NO WAY COMPENSATES FOR THE HEAVY BURDEN OF INDUSTRY-SPECIFIC CONTRIBUTIONS

Industry-specific contributions as a percentage of overall tax rate - 2021		
FRANCE*	SPAIN*	OTHER COUNTRIES OF THE STUDY (Italy, Germany, UK, Switzerland and Ireland),
between 24% and 40%	between 14% and 21%	< 5%

* Depending on company type (distributor, contractor, producer/distributor)

TAX INCENTIVES TO PROMOTE RESEARCH

France faces competition from other countries.



Source : PwC study and analysis of 2021 results conducted for Leem

Here are the quantified consequences

- **6 industry-specific taxes and fees in France** (7 when the safeguard clause is included), compared with just 3 in Spain and Italy, 1 in Germany and 0 in the UK.
- In France, the proportion of total general taxation represented by industry-specific taxation (excluding economic regulation) varies between **24% and 40%** depending on the profile of the pharmaceutical company concerned, compared with between 14% and 21% in Spain, and between 0% and 4% in other European countries.

SO WHAT SHOULD TOMORROW'S TAX POLICY LOOK LIKE?

To strengthen its position in an increasingly competitive international environment, France must implement an ambitious tax policy and reduce the current deviations to an absolute minimum.

Faced with this loss of attractiveness for inward investment, Leem campaigns for **a simplified, stabilised and more affordable tax system**, and promotes a range of measures, including:

- restoring the attractiveness of the Research Tax Credit (CIR) and securing its use;
- converging production-related taxation and industry-specific taxation with those of France's main European competitors;
- adapting industry-specific taxation to take account of the features specific of VSEs and SMEs.



AN EXPLANATION OF THE "FINANCING AND REGULATION OF HEALTH PRODUCTS" TASK FORCE

In October 2022, Leem voiced its concerns regarding the implementation of measures contained in the PLFSS for 2023. The animated parliamentary debates that took place at the end of 2022 led to the formation by Prime Minister Elisabeth Borne at the end of January 2023 of a task force of experts to examine and review the financing and regulation of health products. The ultimate aim of the task force was to propose measures that would reconcile access to treatment for all patients with the challenges around healthcare system attractiveness and sustainability.

At the same time, Leem worked with global consultancy Roland Berger to set up its "Observatoire de l'accès et de l'attractivité de la France" (Observatory to monitor access to medicines and attractiveness in France) to objectively measure the issues of patient access to medicines and the attractiveness of France for industrial inward investment. More frequent shortages, de-industrialisation, a severely downgraded balance of payments, and increasing problems around patient access to innovative treatments in France... there are many genuine reasons for concern (see *the Leem Observatory findings at leem.org*).

The task force set out to interview the full range of French healthcare system stakeholders. **Leem was interviewed three times between January and May 2023, and on each occasion had the opportunity to share its assessment of medicines policy over the last decade and put forward proposals for changes to the ways in which the pharmaceutical industry is regulated and financed.**

The report submitted by the task force broadly confirms Leem's findings regarding the structural problems of the system, which have been exacerbated by both the Covid crisis and the war in Ukraine. Given the impact of unprecedented levels of therapeutic innovation now emerging for patients, **the expert task force recognises that the current regulatory mechanisms are no longer fit for purpose and that the issue of funding is an urgent challenge for the coming years.**

Its recommendations include continuation of the price cuts negotiated between the CEPS and manufacturers within a transparent multi-year framework, ensuring that healthcare products are prescribed correctly, boosting savings generated by medical cost containment through prescription control, and even setting a target for a rapid reduction in the safeguard clause to return it to a level commensurate with past amounts (€500m).

Leem embraces the "new deal" principle proposed by the expert task force, which would involve a concerted root and branch reconstruction of the tools used to regulate and finance medicines in order to reconcile health, manufacturing, environmental and financial goals.

! Leem points of concern regarding the PLFSS for 2024

The economic and financial measures to be announced in the PLFSS for 2024 will be decisive in initiating the trajectory of the “new deal” proposed by the report of the “financing and regulation of health products” task force.

Leem will focus particular attention on these **6 key points**:

- 1. As referred to by the Prime Minister in her letter of 19 December 2022, *revision of Montant M for 2023* in order to *contain the otherwise uncontrolled growth of the safeguard clause*.**
- 2. *Ending the practice of using medicines as a budgetary adjustment variable* by indexing their growth to that of the Ondam from 2024 onwards.**
"Medicines are not an adjustment variable for our health budgets; we have to be consistent", as the French President stressed on 13 June this year.
- 3. *Set a price cut envelope for 2024* that is compatible with targets and goals for the industry and the sustained level of inflation.**
- 4. *Definitively rule out the inclusion of purchases made by Santé Publique France* (the national public health agency) within the regulated envelope.**
- 5. *Permanently set the safeguard clause cap* at 10% of pharmaceutical company net revenue.**
- 6. *Put an end to the mechanism of “communicating vessels” between the various regulatory tools*: price cuts, medical cost containment through prescription control, new reimbursement measures and purchases made by Santé Publique France are all ultimately **guaranteed by the safeguard clause**. Simply transferring savings between regulatory levers will not deliver a satisfactory response to the regulatory pressure to which companies are currently subject.**

ANNEX 1

Resources

- Observatory to monitor access to medicines and attractiveness in France (*Observatoire de l'accès aux médicaments et de l'attractivité de la France*), Roland Berger's study for Leem, June 2023
- For a 'new deal' guaranteeing equal and sustainable access for patients to all healthcare products – Report of the interministerial task force assigned by the French Prime Minister on the financing and regulation of health products, August 2023
- Taxation of the medicines sector in France/Europe, PwC survey for Leem, May 2022
- 2022 Key data on French pharmaceutical industry (*Bilan économique du Leem 2022*)
- Proceedings of the “Reinventing the medicines economic system” symposium, June 2022

ANNEX 2

PLFSS GLOSSARY

- **CEPS:** *Comité économique des produits de santé* (French Healthcare Products Pricing Committee)
- **CIR:** *Crédit impôt recherche* (Research Tax Credit)
- **CNAM:** *Caisse nationale de l'Assurance maladie* (French National Health Insurance Fund)
- **CS:** *Clause de sauvegarde* (Safeguard Clause)
- **CCSS:** *Commission des comptes de la Sécurité sociale* (French Social Security Accounts Committee)
- **CSIS:** *Conseil stratégique des industries de santé* (Strategic Council for the Healthcare Industries)
- **DGE:** Directorate-General for Enterprise
- **DGOS:** *Direction générale de l'offre de soins* (General Directorate for Healthcare Services)
- **DREES:** *Direction de la Recherche, des Études, de l'Évaluation et des statistiques* (Directorate for Research, Studies, Evaluation and Statistics)
- **DSS:** *Direction de la Sécurité sociale* (Directorate for Social Security)
- **JO:** *Journal officiel* which publishes laws and regulations of the French Republic
- **LF:** *Loi de finances* (Finance Act)
- **LPFP:** *Loi de programmation des finances publiques* (Public Finance Programming Act)
- **LFSS:** *Loi de financement de la Sécurité sociale* (Social Security Finance Act)
- **MA:** Market Authorisation (for pharmaceutical products)
- **MECSS:** *Mission d'évaluation et de contrôle de la Sécurité sociale* (Evaluation and Monitoring Mission on Social Security Finance Laws)
- **Montant M (M Amount):** The amount adopted annually by Parliament, above which the aggregated revenue of the pharmaceutical industry must be repaid under the terms of the Safeguard Clause
- **NR:** *non remboursé* (not reimbursed)
- **Ondam:** *Objectif national de dépenses de l'Assurance maladie* (National ceiling for health insurance expenditure)
- **OTC:** Over the counter (medicines available from pharmacies without prescription)
- **PLF:** *Projet de loi de finances* (Finance Bill)
- **PLFSS:** *Projet de loi de financement de la Sécurité sociale* (Social Security Finance Bill)
- **Regulatory tools:** Cost-saving measures applied each year to medicines (price cuts, clawbacks, medical cost containment through prescription control, safeguard clause)
- **RIM:** *réunions interministérielles* (interministerial meetings)
- **Underspending/Overspending:** these terms are used to describe the problems that arise in under-achieving or exceeding the savings targets set by Social Security for healthcare expenditure.

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