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# THE FRENCH SOCIAL SECURITY FINANCE BILL (PLFSS) AND MEDICINES

## An explanation

September 2022

## 10 KEY QUESTIONS ON THE FRENCH SOCIAL SECURITY FINANCE ACT (LFSS)

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# 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 and jargon 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 PLFSS 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.
- **Recent years have been marked by underspending on medicines by the national health insurance,** as a direct result of the pharmaceutical industry making savings in excess of the levels forecast at the time the budget was prepared.
- **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 subsequent adjustment provisions 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) above which all pharmaceutical companies must contribute a proportion of the revenue generated above this threshold level to the national health insurance** *(see page 13)*. Leem pays very close attention to the methodology used to set the '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 understand the economic pressure imposed on medicines

**11,6%** ▸ Total regulated medicines sales are expected to account for 11.6% of expenditure within the Ondam (National Healthcare Spending Target) for 2021 (excluding the Covid-19 and *Ségur de la Santé* healthcare reforms). The figure for 2012 was 13.6%.

**39%** ▸ medicines are required to make the highest contribution of any health sector to achieving national health insurance savings. Overall, savings directly related to medicines accounted for 39% of all savings measures planned at the time the Ondam for 2021 was prepared.

**€760 million** ▸ The '*clause de sauvegarde*' (safeguard clause) figure for 2021 is expected to be €760 million; a figure three times higher than the previous historic high. Originally introduced as a safeguard or safety net to meet unexpected increases in expenditure on medicines, it is now stealthily becoming a regulation tool in its own right.

**53%** ▸ Savings linked to the relevance of prescriptions achieved only 53% of their target for 2019 (the year most recently analysed), at a time when over-achievement of targets was a regular occurrence in respect of price cuts or clawback payments made by manufacturers.

**6** ▸ Over and above the general taxation regime, France applies six industry-specific taxes and fees to pharmaceutical companies; 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)

Définition • 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 the French parliament, it passes into law as the Social Security Finance Act (LFSS, for "*Loi de Financement de la Sécurité sociale*") and is published in the Official Journal in December of each year. So the LFSS for 2023 will be voted on in December 2022.
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);
- 'families';
- '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?

The LFSS is structured in **4 sections**:

- **The 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 second section** relates to the current financial year and takes the form of an amending finance law;
- **The third section** sets the social security revenue estimates;
- **The fourth section** sets the social security spending target, also referred to as the Ondam (National Healthcare Expenditure Target, or in French "*Objectif national de dépenses de l'Assurance maladie*").

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

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

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

- ➜ Open Appendix 7 (budget balances and savings measures) and go to **the Ondam Construction paragraph**.
- ➜ Search (<ctrl> F), the text of the PLFSS using the keywords '*médicament*' (medicine) and '*enveloppe M*' (the M amount envelope) and **view the explanatory statement in each article**.
- ➜ 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 (Social security policy evaluation report) to track the trends of multiple indicators (especially the results of the savings linked to the relevance of prescriptions).

## 4• How is the PLFSS prepared? By whom and when?

Multiple contributors are involved in working on the PLFSS throughout the year, but the majority of the work involved is concentrated into the autumn months.

### GOOD TO KNOW

As with Finance Acts,
**the LFSS comprises four sections:**

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

### THE TIMEFRAME OF THE PLFSS

## BEFORE SUMMER

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

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

## 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 (PLF) and PLFSS, as well as the specific measures covered by the text, in a number of interministerial meetings (RIMs) held during 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 and debate in the Senate between October and December, the text is evaluated several times throughout the following year.

## THE FOLLOWING SPRING

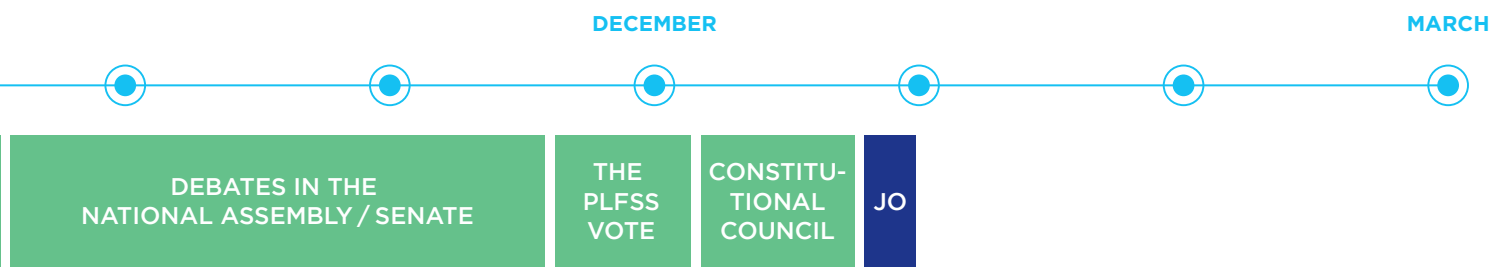
Every year, **the *Cour des comptes* (Court of Audit)** publishes two reports that have a structural impact on social security issues: the general social security system accounts certification report in the spring of the following year (essentially an accounting report), followed in the summer by the report on implementation of social security finance laws, which formulates proposals for reforms designed to maintain a viable forward trajectory for the public accounts.

## JUNE TO SEPTEMBER

**The *Commission des comptes de la Sécurité sociale* (Social Security Accounts Committee)** chaired by the Minister of Health 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 *mission d'évaluation et de contrôle de la Sécurité sociale* (Evaluation and scrutiny task force on Social Security Finance Acts) or MECSS**, a body reporting to both chambers of parliament, is officially appointed as the body with organic responsibility for monitoring and inspecting LFSSs.

**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).



## 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 and controlled on a regular basis.

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 of the PLFSS of a '*compteur des écarts*' (deviation meter) to compare the expenditure as forecast in the public finance programming act (LPFP) 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 reduce them.

*N.B. : At the current stage of implementation of this organic law, it seems unlikely that the level of detail provided 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 expenditure sub-targets: outpatient care and inpatient care.

From the pharmaceutical company perspective, the LFSS is a channel for dialogue with the legislator. It is the only opportunity for public discussion of medicine 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, with an inevitable emphasis on savings. Any overview of the challenges facing the pharmaceutical industry to inform the decisions made by members of parliament is unfortunately absent from debates, 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 pharmaceuticals market. *(see Fact Sheet 1, Medicines: a regulated economy)*.

## 7• Focus on the Ondam

Ondam stands for National Healthcare Expenditure Target (in French "*Objectif national de dépenses de l'Assurance maladie*"). 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 national health insurance:

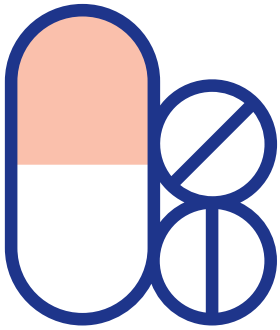
1. **Outpatient expenditure**, including one part of expenditure on medicines;
2. **Expenditure on healthcare facilities (Inpatient care)**, including the other part of expenditure on medicines;
3. **Expenditure on care and services for the elderly**;
4. **Expenditure on care and services for people with disabilities**;
5. **Expenditure on the regional action fund**;
6. **Other care expenditure centres**.

The Ondam is prepared on the basis of several indicators, including expenditure forecasts for the previous year, the upward trend in expenditure, and new cost savings measures.

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

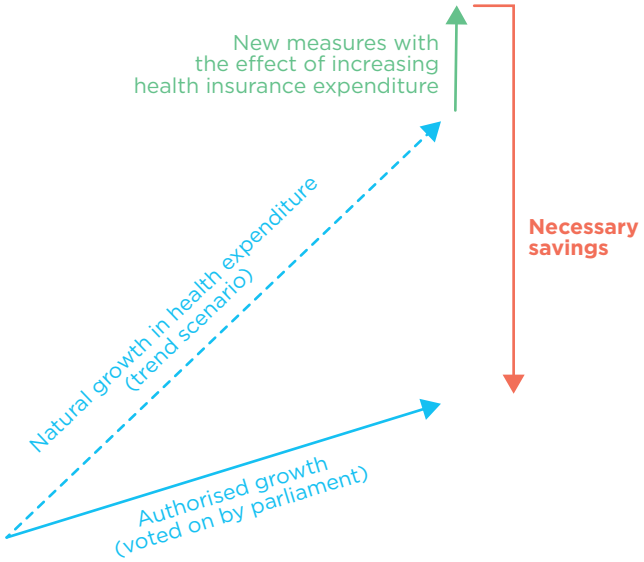
The LFSS is a structural element of the French reimbursed medicines market dynamics, because it defines the level of growth 'acceptable' to the State in respect of expenditure of medicines, the overall level of savings required and the measures needed to deliver the level of savings.

Medicines make the largest contribution to health-care system savings: in 2021, they contributed around 39% of all the savings made as a result of the Ondam *(see Fact Sheet 2, The four levers of medicines regulation)*.



**THE NATIONAL HEALTH INSURANCE EXPENDITURE TARGET (ONDAM)**

**Authorised growth rate and savings**




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.

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

Pharmaceutical companies see **two types of deviations:**

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

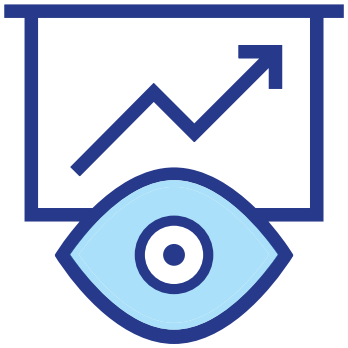
UPSTREAM

▸ **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.

The Social Security accounts are not effectively prepared until March/April of the following year. But even when the real data are known, the major balances of the social security budget are not revised accordingly. The pharmaceutical companies find this state of affairs deplorable. 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

### ▸ The accounting perspective versus the 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 its forecast?

2. **The regulatory perspective:** have the savings measures sufficiently slowed the spontaneous growth in sales of reimbursable medicines?

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 government on this issue.
The only information shared publicly is that relating to individual regulatory levers: **the activity report of the *Comité économique des produits de santé* (healthcare products pricing committee) or CEPS** simply provides figures on the savings made through price cuts and clawback payments. An estimate of savings made as a result of medicalised prescription control is included in **the social security policy evaluation report** *(Appendix 1 to the LFSS)*.

The Social Security Accounts Committee (CCSS) 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.

DOWNSTREAM

### ▸ Overspending and underspending

Overspending means expenditure is higher than the level foreseen 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).

➜ **Recent years have been mainly marked by excessive savings as a result of price cuts and clawback payments** *(see Fact Sheet 2, The four levers of medicines regulation)*. **Successive LFSSs have increased the role of clawback payments to the point where they are now the main lever for savings on medicine expenditure.**

➜ **Medicalised prescription control measures** *(see Fact Sheet 2, The four levers of medicines regulation)* **have been underachieved 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.**

In recent years, there has been a consistent pattern of excessive savings on medicines as a result of strong market dynamics in combination with underspending. The result is that the pharmaceutical industry can then be taxed on its growth, at the same time as the national health insurance can underspend on its forecasts for reimbursed medicines.

# 10• Why is rebasing necessary?

Rebasing refers to retrospectively adjusting the multi-year expenditure trajectory set in advance by the government as part of the LFSS to reflect reality.

This in-year adjustment mechanism avoids the pitfall of forecasts being carried forward from year to year, and therefore **avoids financial deficits from being carried forward.** 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.

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

- **a revenue base**, reflecting market conditions at the time the LFSS is voted on in parliament, and is therefore a forecast (*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.

Divergences 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 subsequent years on several recent occasions. So the decision taken regarding the regulation of medicines within the LFSS has failed to meet growth needs and achieve the targets set. In a few rare instances, it proved possible to make a retrospective correction in the next 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 forecast at the time of LFSS preparation.

The regulatory mechanism for the current year would then be adjusted as and when necessary if the actual baseline (previous year) were to diverge from the forecast made at the time the LFSS was prepared. 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 pharmaceuticals industry.

It was at this event that 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% of revenue, corresponding to 1% of reimbursed expenditure for all medicines over three years».*

Reformed that year, the all-new *enveloppe M* budget was set on the basis of 0.5% growth in estimated net revenue for 2018, minus the effect of the safeguard clause, (*N.B. given the change of system in 2019, this was a theoretical safeguard clause amount, recalculated as if the reform had applied in 2018*).

**M amount envelope budget for 2019 = 1,005 x [(Net sales for 2018) – (estimated safeguard clause repayment)]**

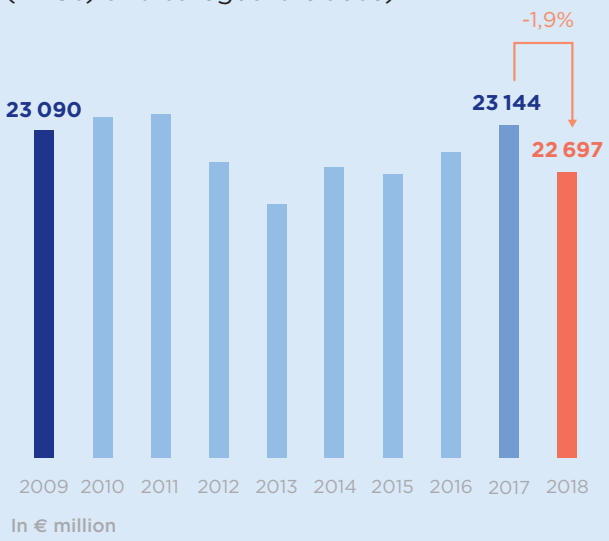
At the end of the 2018 accounting period, the outcome was uncontestable: the savings made were excessive in 2018 and, despite higher than expected natural market growth, net revenue was much lower than forecast.

- **Price cuts: +€225 M million in savings** (€995 million actual, rather than the €870 million forecast))
- **Clawback payments: +€340 million in savings** (€552 million of additional clawback payments received relative to 2017, rather than the €210 million forecast)

→ **Underspend on medicines: –€435 million reported by the Social Security Accounts Committee**

The baseline effect therefore produced a very unfavourable outcome: at the level of growth previously announced (+0.5%), the deviation between the actual figures for 2018 and the estimates made the previous summer had resulted in a 2019 M amount envelope budget 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** (outpatients and inpatients)**, NET OF ALL REPAYMENTS** (product clawback payments, temporary authorisations for use (ATUs) and 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.

**2019 growth rate in the LFSS for 2018**
(commitment made at 2018 CSIS)
**+ 0.5 %**

↓

**Actual growth rate for 2018**
**- 1.9 %**

↓

**2019 growth rate in the LFSS for 2019**
**+ 1 %**

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 Social Security Accounts Committee then notes that the actual expenditure on medicines by the national health insurance in 2019 again fell far below the forecast accounts used in the process of preparing the Ondam:

- **Price cuts: + €230 million in savings** (€1,191 M million actual, rather than the €960 million forecast)
- **Clawback payments: +€130 million in savings** (€330 million in additional clawback payments received relative to 2018, rather than the €200 million forecast). **This excessive level of savings would rise even further to €900 million were the 'delayed' clawback payments reallocated.**

  → Underspend on medicines: - €260 million reported by the 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 taxation, despite the fact that the national health insurance had spent €260 million less than forecast on medicines.**
- **Given the excessive implementation of regulation measures, it was only this accounting transaction that made it possible to meet the French President's commitment to 1% growth in 2019.**

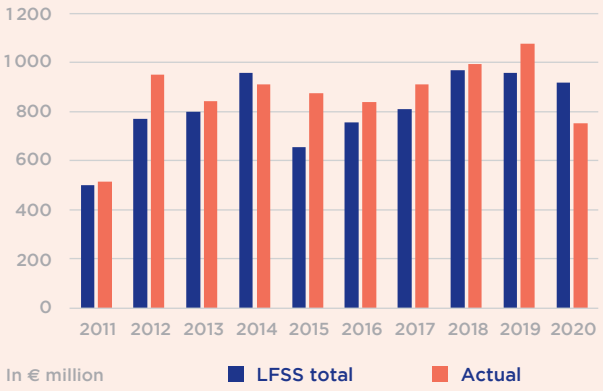
# ADOPTED *VERSUS* ACTUAL

For more than a decade, there has been a deviation between the amounts voted on by parliament within the framework of the LFSS and the reality experienced by pharmaceutical companies the following year.

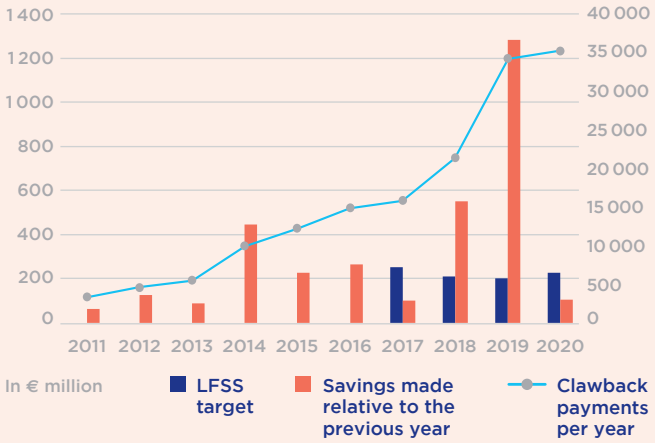
The savings made in recent years as a result of price cuts and annual clawback payments made by companies have almost always been excessive, whereas savings on medicalised prescription control (prescription relevance) measures have been significantly under-applied.

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 the net sales growth of pharmaceutical companies over the last 10 years is zero, despite the fact that members of parliament vote to approve revenue growth for the industry every year when they adopt the LFSS.

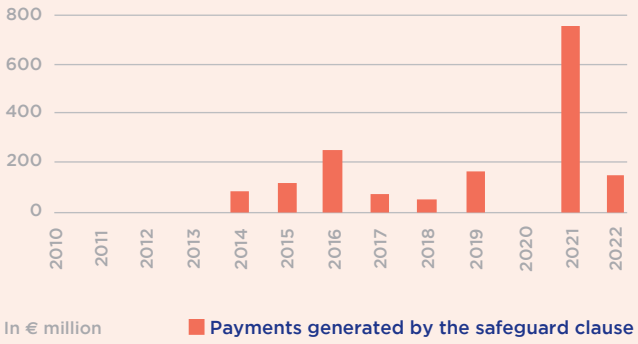
## Excessive price cuts



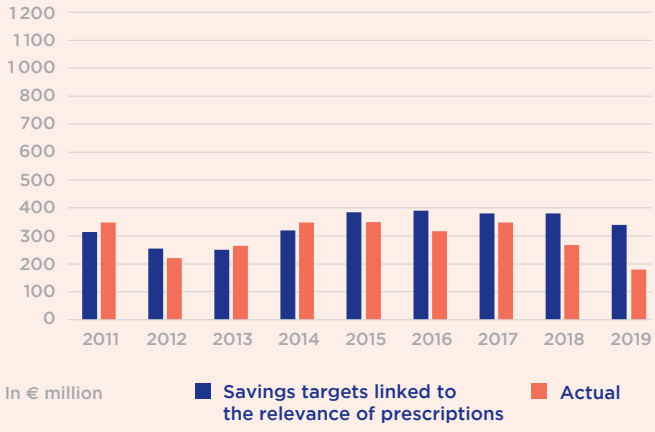

## Exponential growth in clawback payments



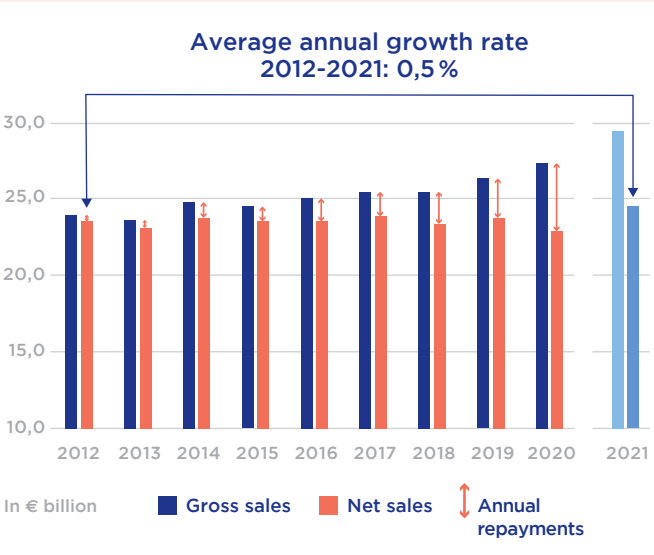

## Systematic triggering of the safeguard clause




## Relevance of prescriptions: a source of savings to be revitalised




## Gross sales *versus* net sales



Fact Sheet 1

# Medicines: a regulated economy (2012-2022)

## Definitions

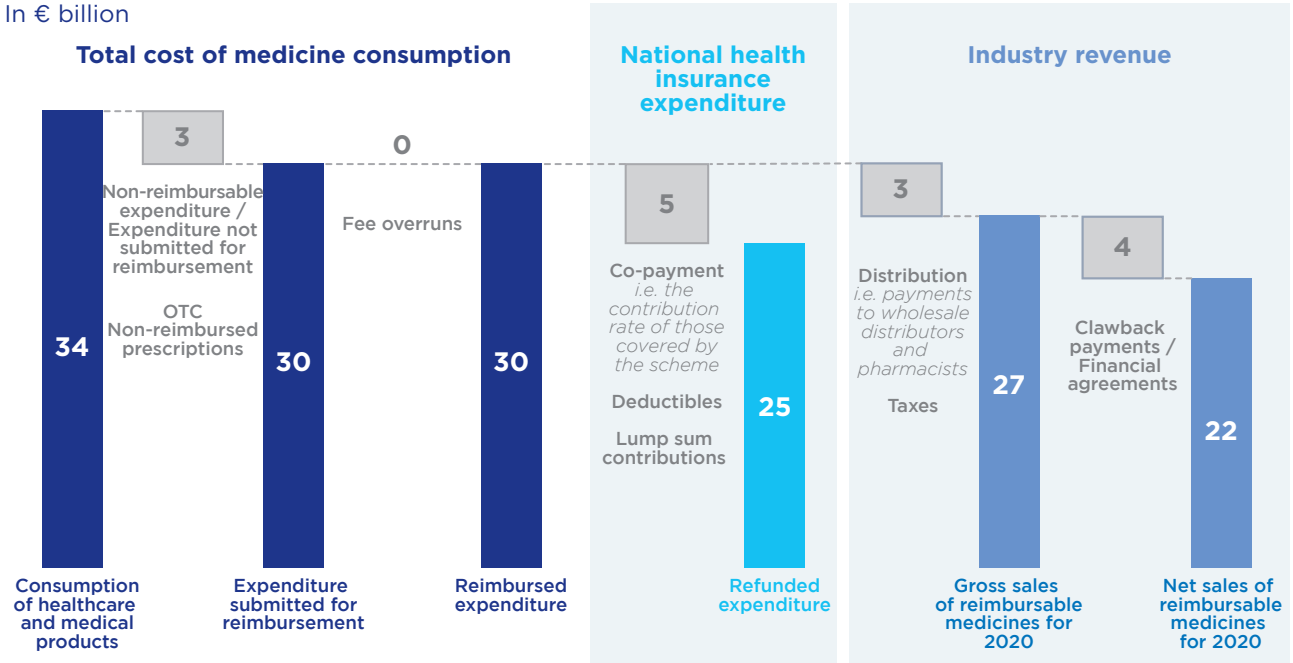
**The term 'regulated net sales of medicines'** refers to industry revenue generated through sales of all the medicines eligible for reimbursement via the national health insurance, as regulated in the Ondam national health insurance expenditure target for inpatients and outpatients, minus the contractual or compulsory clawback payments 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 revenue to the national health insurance is referred to as **the 'M Amount'**, and the actual payment as **the 'M contribution'** or **'safeguard clause' contribution**.

## National health insurance expenditure or industry revenue: two parallel perspectives

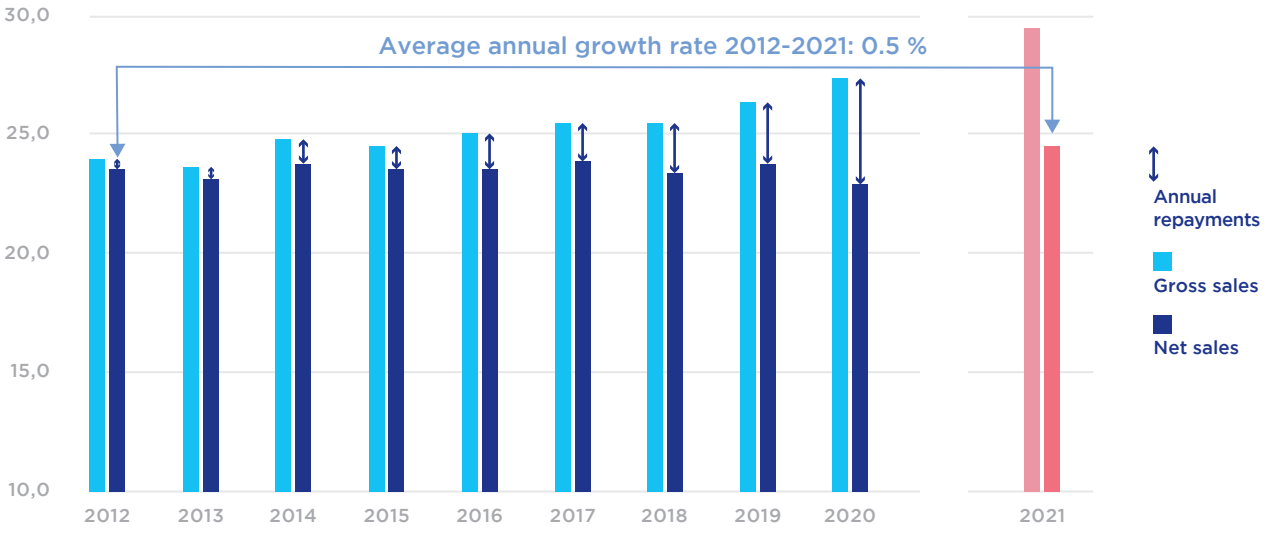
> ***N.B.:*** *the contribution made by those covered by the scheme is equivalent to 100% minus the reimbursement rate set by the national health insurance.*

In € billion




*Source : DREES 2021 Health Accounts (2020 data), Fact sheet 11*
*Data from the 2020 CEPS AR*

# Findings: zero growth




In € billion

Between 2012 and 2020, growth in the budget allocated to the pharmaceutical industry (in the Social Security health expenditure envelope) remained sluggish because it was effectively neutralised by annual clawback payments *(see Fact Sheet 2, The four levers of medicines regulation)*.

In 2021, fallout from the Covid-19 crisis combined with an historic tidal wave of innovation to bring about a step change in the trend of the previous decade, but at the cost to the industry of colossal clawback payments.

Health expenditure within the Ondam perimeter rose by an average of 2.3% over this period. In mechanical terms, the ratio between net revenue from sales of medicines and Ondam expenditure decreased year-on-year. From 13.6% in 2012, it had fallen to 11.6% in 2021.

| | 2012 | 2021 |
|---|---|---|
| **Regulated net sales for medicines** | 23,5 | 24,5 |
| **Ondam excluding Covid-19/Ségur healthcare reforms** | 172,4 | 210,7 |
| **Adjusted ratio of net sales/Ondam** | 13,6 % | 11,6 % |

# Decoding the measures contained in the Healthcare 2030 Innovation Plan

On the basis of work carried out by the Strategic Council for the Healthcare Industries (at the 2021 CSIS), the French President committed to a healthcare product growth rate of 2.4% over a three-year period. This commitment appeared in the LFSS in the form of 'authorised' growth in medicines of 2.2% for 2022 (on the basis of total reimbursements).

In terms of converting expenditure to revenue (the benchmark metric used by the industry), this has resulted in an 'M contribution' 1.7% higher than the industry's net revenue for 2021. The conversion rate used has not been disclosed.

## MEETING THE COST OF COVID TREATMENTS OUTSIDE THE ONDAM

Unlike the majority of treatments, vaccines and some other Covid-19 treatments are not included in the figures for expenditure on inpatient and outpatient care. They also fall outside the 'M-envelope' that triggers the safeguard clause.

**The purchase of vaccines and the cost of these treatments are the responsibilities of the National Public Health Agency (Santé Publique France), whose funding has been included in the 6th sub-target of the Ondam — 'Operators funded by the national health insurance' since 2020.**

Fact Sheet 2

# The four levers of medicines regulation

## Medicines are the main contributors to the savings measures included in the LFSS

In 2021, the LFSS determined that the total revenue generated by regulated medicines should contribute 11.6% 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 part of regulation measures is significantly higher, with medicines alone contributing 39% of the savings incorporated into the Ondam as part of its preparation.

**In 2021, the Social Security system was required to meet significant levels of exceptional expenditure:*

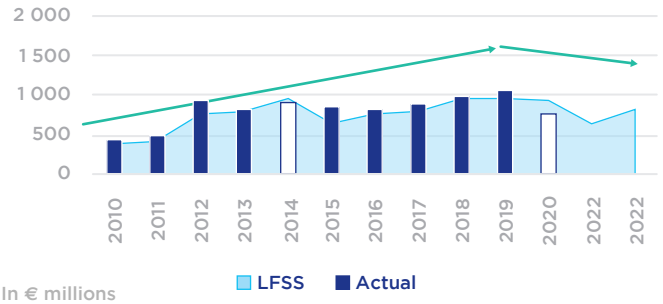
- *more than 8 billion for the systemic measures introduced in the* Ségur de la santé *healthcare reform;*
- *the additional cost of measures introduced during the Covid-19 health crisis totalled around 15 billion.*

## 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 'M contribution' payment reduction allowance (*see the Focus pages at the end of this fact sheet*).

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

## PRICE CUTS




In € millions

1

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

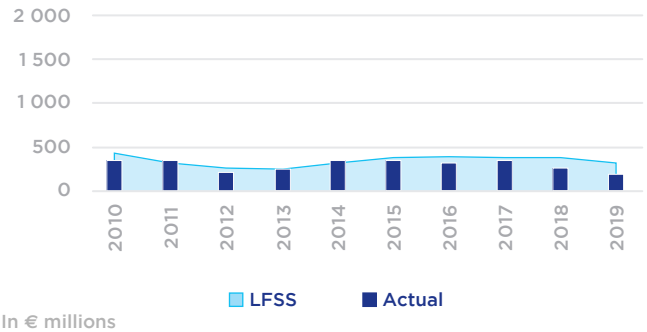
## CLAWBACK PAYMENTS


In € millions

2

**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% of listed products are subject to a negotiated price), but in some specific cases (e.g. early access products), they are set by law.

## RELEVANCE OF PRESCRIPTIONS CONTROL

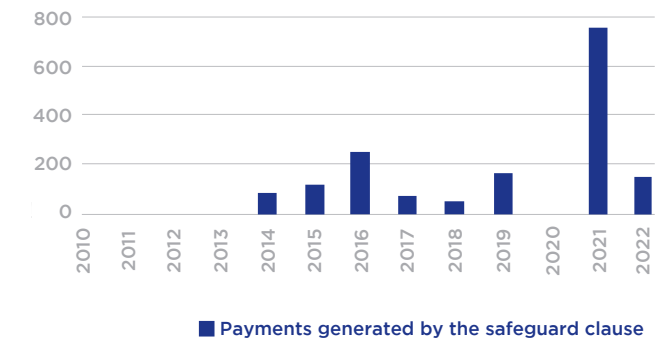



In € millions

3

**Medicalised prescription control** refers to actions implemented by the national health insurance (with the aim of improving the relevance of prescription and the consumption of medicines).

## SAFEGUARD CLAUSE




In € millions

4

**The safeguard clause** is triggered when the net revenue generated by medicines exceeds the M amount voted on by parliament in the LFSS.

Clawback payments are now the main lever for savings on medicines.

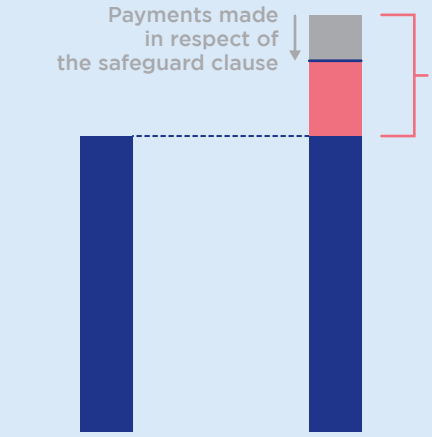
FOCUS

# The safeguard clause

The **'M contribution'**, also known as the **'safeguard clause' contribution**, is a contribution payable by companies providing one or more medicines when the revenue generated by certain proprietary pharmaceutical products —excluding tax and net of clawback payments— in mainland France and the overseas departments exceeds the preset 'M amount' 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 an authorised rate of growth relative to the pre-tax sales generated in the previous year. Since the LFSS for 2021, it has been a fixed amount voted on by parliament.

## How does the safeguard clause work?




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

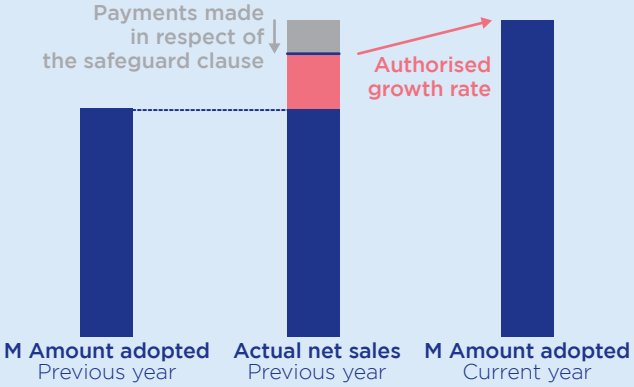
**Manufacturers return a proportion of the revenue generated over and above the fixed amount set by the LFSS on the basis of a progressive scale:**

| | |
|---|---|
| **< 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**

- **The contribution for each company is calculated individually**
  Pro-rata the revenue generated within the scope of the safeguard clause
- **Each 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

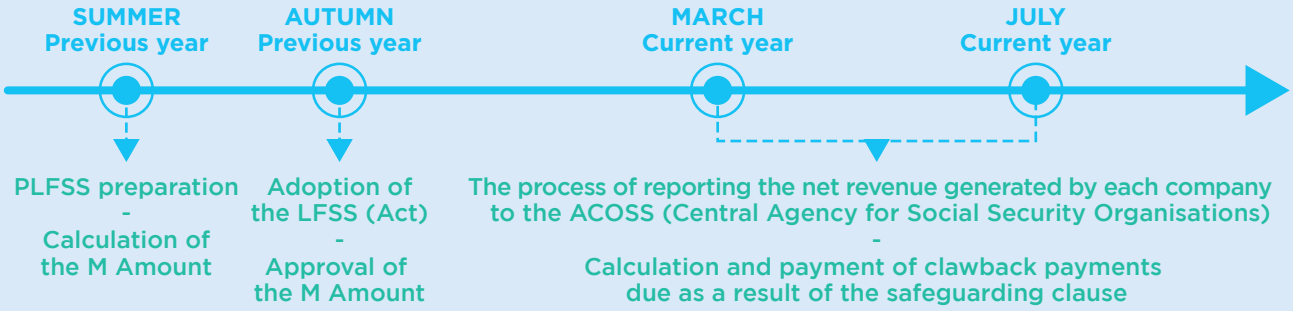
## How is the M amount calculated?




The methodology used to calculate the M amount is not fixed by law. Historically, and following the triggering of the safeguard clause, the government adopted a calculation methodology that can be summarised by this formula:

**M Amount = (net sales of the pharmaceutical industry – safeguard clause) x growth rate**

## From the setting of an M Amount to the clawback payments made by companies




In practice, recurrent delays in this procedure make the 1 July legal payment deadline a very theoretical date. In recent years, the final amount of the contribution has not been notified until Quarter 4 of the following year.
As a result, the pharmaceutical industry net sales figure for the previous year remains unknown at the time the PLFSS is prepared, 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 regarding the Social Security accounts for 2021.

## 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. Estimates shared in September 2022 by the Ministry of Health predict safeguard clause payments of around €800 million in respect of 2021: a level three times higher that the industry's previous maximum contribution of 2016.
The LFSS for 2022 was the first to include a safeguard clause performance target. It seems likely that this target of €125 million will be significantly exceeded. The safeguard clause is therefore now a fully-fledged instrument for regulating expenditure.

## 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 sales generated in the current year by all companies in regulated medicines market. This estimate is usually prepared on the basis of the previous year's data.

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

- the current year net sales 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 regulation 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 medicalised prescription control.

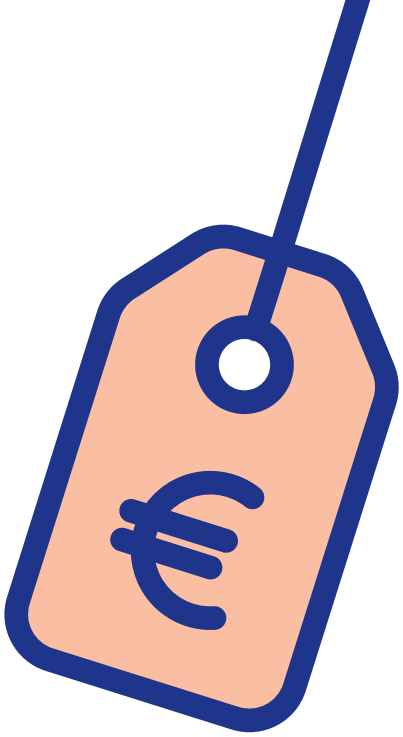
As discussions around the PLFSS for 2022 have highlighted, the same difficulties are shared by government. An amount of €400 million as a result of the safeguard clause for 2021 had originally been suggested by government. However, the latest data shared by the DSS (September 2022) indicate that this figure is likely to be twice that suggested by initial estimates.

**These differences between estimates and reality 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; for example, these retrospective changes may result in companies having to revise their financial statements for the previous year.

Fact Sheet 3

# Medicine prices in France



**It is important to remember that the price of a medicine is not set as part of preparing the LFSS!**

## Who sets the prices of medicines in France?

The French Healthcare Products Pricing Committee (CEPS), which reports to the Ministers of Health, Social Security and the Economy, is required by law to set the prices for those medicines covered by the compulsory health insurance. 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 outpatient medicines... *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 Official Journal.

Medicines remain one of the final few sectors to be subject to official price controls in France.

***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 drugs 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 the T2A (DRG-based funding);*
- *medicines on the 'liste de rétrocession' (medicines that can be sold to outpatients in hospital pharmacies). This is a dispensing restriction specific to certain products, for which the hospital pharmacy stands in for the community pharmacy.*

# How are medicine prices set?

**THE MEDICINE PRICE NEGOTIATION TAKES PLACE AT 3 LEVELS**

### LEGISLATIVE

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

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

### POLICY

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

### CONTRACTUAL

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

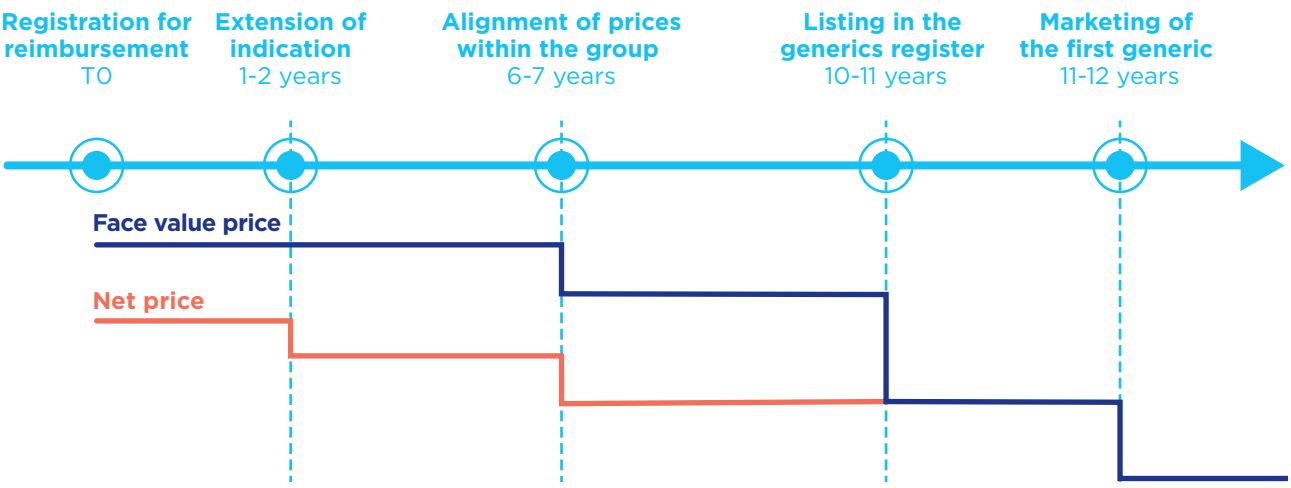
Medicines considered innovative by the Transparency Committee may benefit from a 'premium' price relative to those therapeutic solutions already available in the market.

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 pharmaceutical product is subject to an initial markdown (-40% for a chemical-based medicine and -20% for a biological medicine), followed by subsequent periodic markdowns related to the market penetration rate of the relevant generics or biosimilars. These various markdowns 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 therefore have a gross price, which is published in the Official Journal, and a net price reflecting deduction of these clawback payments. These clauses may be agreements based on economic or public health criteria. In 2020, only 4% 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 industrials 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 implementation of remuneration based on fee for service or public health targets. As a result, a number of types of dispensing fee have been introduced (for medicines specific to certain conditions, including age). 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 important in the case of generics.

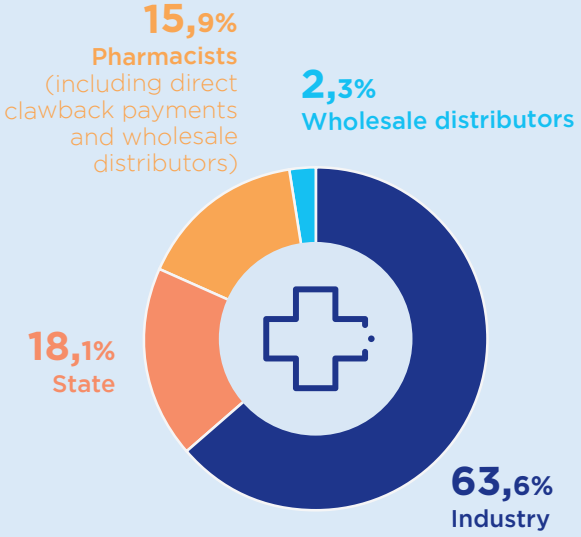
**PFHT = the pre-tax ex-manufacturer price**
The price negotiated between the CEPS and the manufacturer

**PGHT = the pre-tax wholesaler price**
PFHT plus a margin of 6.93% of the PFHT for remuneration of wholesale distributors (GRs), capped at €32

**PPHT = Pre-tax public price**
PGHT plus a degressive margin of between 5% and 10% of the PFHT, capped at €97

**PPTTC = Public price including VAT**
PPHT plus VAT charged at 2.1%

**AVERAGE BREAKDOWN OF VAT-INCLUSIVE SALES OF REIMBURSABLE MEDICINES SOLD THROUGH DISPENSING PHARMACIES IN 2020**

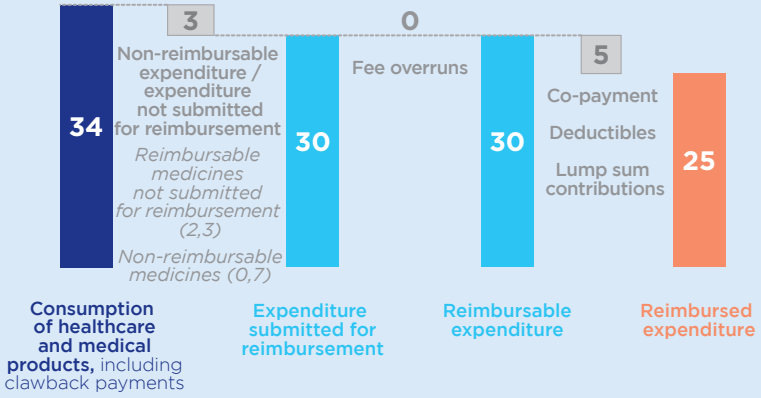


## Who pays for the reimbursement of medicines dispensed through community pharmacies?

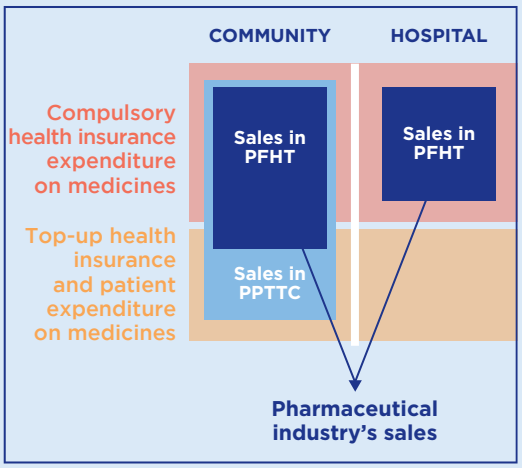
There are **currently four reimbursement rates** for medicines in the General Social Security Scheme (funded by the compulsory health insurance):

- **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 offering low levels of Actual Medical Benefit The remainder is met 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 FUNDING OF MEDICINES BY THE NATIONAL HEALTH INSURANCE** (IN € BILLION)




*(Source : DREES, comptes de la santé 2021 (données 2020), fiche 11)*




## Who pays for the reimbursement of medicines dispensed through hospital pharmacies?

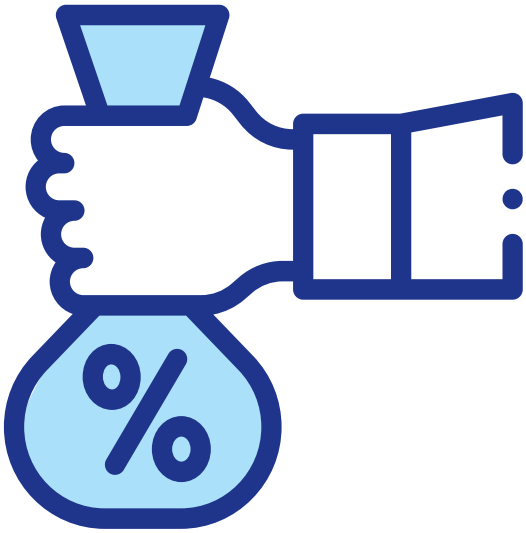
Hospital-dispensed medicines fall into two categories:

- medicines covered by the fees charged for procedures by healthcare facilities, where these have been purchased via a tendering structure and equate to overheads;
- medicines funded via the '*liste en sus*' and those on the '*liste de rétrocession*', which are priced at national level by the CEPS, and are 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 purchase amount and adds a 'premium' in the form of a fraction of the difference between that amount and the price set by the CEPS. This mechanism, known as the 'écart médicament indemnisable' (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 a clawback payment agreement is in place between the manufacturer and the CEPS.

Fact Sheet 4

# 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 on basic sales;
- additional sales-based contribution;
- contribution based on expenditures for the promotion of medicines;
- taxes on direct sales;
- fees for filing marketing authorisation (MA) applications;
- environmental taxes (especially in respect of EPR*).

* Extended Producer Responsibility

## What effects does this level of taxation have on pharmaceutical manufacturing in France?

The French tax burden on the pharmaceutical sector 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 reshore 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).*

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 14% to 21% in Spain, and 0% to 4% in other European countries.

- **Of the 404 medicines** authorised by the European Medicines Agency (EMA) between 2016 and 2020 (generics and biosimilars), **only 33 have been produced in France**, compared with 82 in Germany, 68 in the UK, 62 in Ireland, 42 in Spain and 34 in Italy.



## What should tomorrow's tax policy look like?

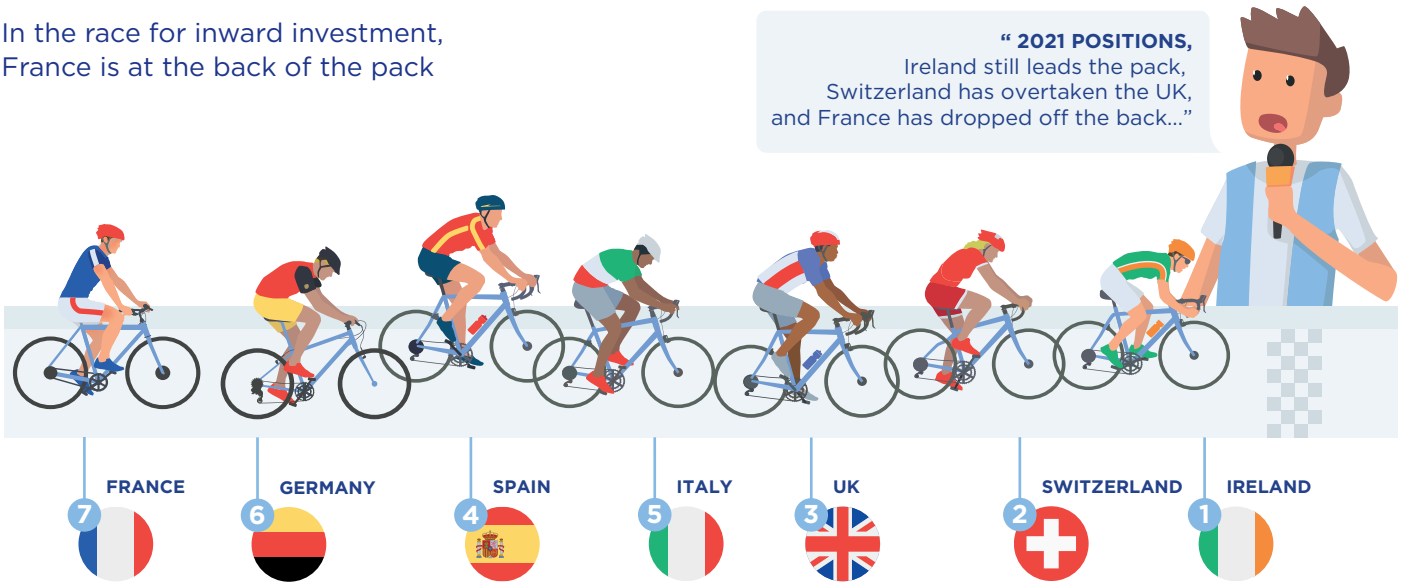
To strengthen its position in an increasingly competitive international environment, France must implement an ambitious tax policy and reduce the current deviations to an absolute minimum.

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 (RTC) and securing its use;
- converging production-related taxation and industry-specific taxation with France's main European competitors;
- adapting industry-specific taxation to take account of the special features of VSEs and SMEs.

# THE TAX TREATMENT OF PHARMACEUTICAL COMPANIES

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




## IMPROVING FRENCH GENERAL TAXATION...

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

## ...CANNOT COMPENSATE 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), |
| 24% to 40% | 14% to 21% | <5% |

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

## TAX INCENTIVES TO PROMOTE RESEARCH

France faces competition from other countries.


*Source : Study and analysis of 2021 results conducted for Leem by PwC.*

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