



Manifest

for the development
of selfcare in France

What the French people expect,
what our health care system needs.

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SELF CARE IN FRANCE

main facts to keep in mind!

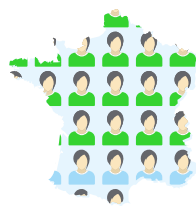
THE FRENCH PEOPLE ARE READY BUT NEED TO BE SUPPORTED



79%

of the French people

are aware of the necessity to reform the French health care system².



80 %

of the French people

have self-medicated over the past 12 months².

SELF-MEDICATION : FULLY FLEDGED, GENUINE MEDICINE, EASILY ACCESSIBLE AND DELIVERED BY EXPERTS



AMM

Self-medication medicine has a marketing authorisation (Autorisation de mise sur le marché, AMM) which guarantees its efficiency and safety.



4.69 €

average price

of self-medication medicine in France versus 6.16 €* in Europe¹⁶.



2.1 %

is the recommended VAT rate

for self-medication medicine. The current 10% rate is too high.



22 192

pharmacies

country-wide provide fast and easy access¹⁵.



Half

of the French people

ask their pharmacist for advice¹⁰.

* This price is calculated on optional medical prescription medicine, reimbursable and non-reimbursable.

A SATURATED HEALTH CARE CHAIN



10.3%

fewer GP's

than in 2007 and numbers are still dropping⁷.



15 million
French people

suffer from a chronic disease which necessitates regular, attentive medical supervision⁹.



55%

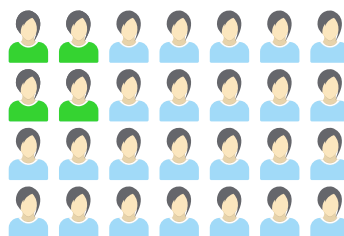
of the French people

have already experienced difficulties in obtaining a medical appointment with a specialist⁵.



108%
occupation rate

of emergency wards⁶.



16/100

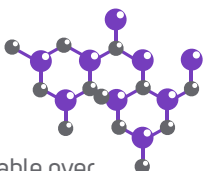
patients seen in consultations could have self-medicated².

POTENTIAL OF THE SELF-MEDICATION RESPONSIBLE MARKET IN FRANCE

90

molecules

could become available over the counter if France were aligned with neighbouring European countries¹².



32.10€

spent on average

by people living in France versus 45.8 euros in Europe¹².



+1.5

billion

euros savings

in one year by developing self-medication¹⁷.



WHAT IS SELF CARE ?

For the World Health Organisation (WHO), selfcare is “what people do for themselves to establish and maintain health, prevent and deal with illness”.

In other words, selfcare means an individual pays preventive attention to his hygiene, nutrition, sports activities, and the treatment he takes by himself via **responsible self-medication**.

	OPTIONAL MEDICAL PRESCRIPTION		MANDATORY MEDICAL PRESCRIPTION
Reimbursable medicine	NOT PRESCRIBED	PRESCRIBED	
Non-reimbursable medicine	NOT PRESCRIBED	PRESCRIBED	
Medical devices	NOT PRESCRIBED	PRESCRIBED	
Foods supplements	NOT PRESCRIBED	PRESCRIBED	*
Self-medication scop			

* Specific case - presence of melatonin (> 1 mg by mouth)

01. INTRODUCTION

In 2020, the current deficit of the Public Health Insurance will have doubled to reach 14 billion euros, before it probably reaches nearly 29 billion euros in 2030 and over 41 billion euros in 2040¹.

This alarming projection results from an analysis by the High Council for the Future of the Public Health Insurance (Haut conseil pour l'Avenir de l'Assurance Maladie, HCAAM) on how to avoid an economic and health disaster; it underlined "the dramatic necessity to control health care spendings, by mobilising numerous sources to increase the efficiency of the health care system". **This opinion is shared by 79% of the French people, who consider that our health care system is in danger and must be reformed².**

We believe that controlling health care spendings will be accomplished by better allocating them, which will necessitate realigning the structure of the current system.

Would it indeed make sense to save at all costs a system which was perfectly adapted to 20th century constraints, when risks were short-term and diseases were acute, but which cannot provide an adequate response to current needs, which are those of chronic diseases and patients living longer with severely deteriorated health conditions?

Some people believe in appealing to the sense of responsibility of patients regarding health care spendings. We agree with that concept, provided appealing to the sense of responsibility is based on a constructive, participation-oriented approach, which does not blame or forbid. We believe in giving the patient the means to act upon his own health, in an autonomous way, to benefit himself and the community.

We are strongly convinced of the need to empower the patient in other words, give him more autonomy and responsibility. This will necessarily go along with the development of selfcare, is key to enable us to move from a health system (which re-establishes health) to a health care system (which prevents disease).

In other words, we need to promote a system able to provide the leeway which our Public Health Insurance needs to invest in research and build more efficient, cost-effective therapeutic responses.

→ **Selfcare is the best way to maintain in – if not bring back to – the center of our health care strategy, the triad of freedom of the parties, equal opportunities to stay in good health and solidarity of care financing.** ●



This booklet and 15 minutes of your time should convince you of the major importance of the development of selfcare.

At the very least, it will show you the economic and social potential of selfcare and the pragmatic ways to encourage it in France.



“ Today’s alarm clock marks a painful wake-up: Sophie’s head feels like it weighs a ton. A quick glance in the bathroom mirror, she looks like a mess. It hurts when she swallows, her nose is running...

In the shower, she nevertheless smiles as she reminds herself that when her Mum calls her at lunch-time, she mustn’t breathe a word about the way she feels. That is, if she wants to avoid the usual speech on how she should immediately run to her GP to “squelch it in the egg”.

The fact is that Sophie finds it really difficult to make her Mum understand that all the GP can do for her, based on her symptoms, is prescribe paracetamol and cough syrup. What is the point ? As if she had plenty of time during the day to waste 30 minutes in a crowded waiting room and spend 23 euros for something she can get over-the-counter at the pharmacist’s.

As she brushes her hair, Sophie thinks that this is always at this point in the conversation that her Mum counter-attacks with “it’s reimbursed, why not take advantage of it, why do you think you pay taxes? Health is important...”. A speech which only ends when Sophie answers mockingly: “And who will pay for my cancer, Mum, if I finish emptying out the Health Insurance funds ?” ; that knock-out blow terminates the fight, her Mum sighs and hangs up, threatening her of a thousand misfortunes.

Only 200 meters away, Sophie enters the pharmacy. 5 minutes and 5 euros later, the problem is solved: she leaves with 2 medicines formulated to treat rhinitis like hers. She chose them herself: paracetamol in stick form to take it immediately in the street (even without her bottle of water, which chose to stay at home!) and throat sweets to ease swallowing and enable her to drink her coffee with Aurélie when she gets to the office: under no circumstances will she skip that first cup of coffee.

The pharmacist validated her choice after 3 questions on her pain and allergies, as always... Sophie smiles again, it seems the whole world has decided to take care of her. She also thinks that if her symptoms haven’t disappeared in 2 days, she will go see her GP and she can call her Mum at that point...

”

**Sophie practices selfcare
and prepares her future...**

02. SELF CARE FACTS

Selfcare a practice which must be valued ... and better supported!

“ I am able to recognise a gastro when I have one... Who isn't? Frankly, seeing my GP for that, when I know exactly what to take, I don't see the point.

At worst, if I'm not sure, I ask my pharmacist who has known me for years! He tells me what to get and that's the end of it ”

Sophie to Aurélie, over a cup of coffee

Selfcare according to Afipa

Selfcare is a practice which responds to the need expressed by patients who want to be more autonomous in the treatment of their benign pathologies, supported by advice given by a health specialist, in particular a pharmacist.

Responsible self-medication is one of the components of self-care. It consists in dealing with benign symptoms thanks to medicine available over the counter, without a medical prescription. It is a responsible practice not to be confused with misuse, which is the non-compliant use of a medicine.

Afipa associates selfcare with three types of products: self-medication medicines, medical devices and food supplements (authorised, available without a medical prescription and therefore not reimbursed, safe and efficient under the indicated conditions of use).

Afipa considers both relevant and necessary to extend the current scope of indications to monitoring the benign symptoms caused by chronic diseases, following a preliminary medical opinion for example migraine and arthritis flare-up?

→ The French people are ready... but need to become more confident! ●



PRECONCEIVED IDEA N° 1

"French people are not prepared to treat their benign health issues by themselves!"

91% of the French people consider themselves capable of dealing by themselves with their benign health problems and their symptoms².

91% of the French people consider themselves capable of dealing by themselves with their benign health problems². This number reflects the evolution of mentalities: patients want more autonomy in the treatment of their health issues and feel they need to be able to treat themselves without calling upon a GP if they don't consider it necessary.

When patients are asked what they are prepared to do to make our health care system sustainable, **71%² of them mention autonomous treatment of their benign health issues with directly available over-the-counter medicine**, in compliance with the use conditions indicated, **with pharmacist advice** (all conditions required to qualify as responsible self-medication); those 71% also declare having self-medicated in the 12 preceding months.

But there are also 43% of the French people who fear interactions between medicines and 20% who fear they might choose the wrong medicine², even though the pharmacist's advice, which is absolutely mandatory when selling self-medication medicines, guarantees the right choice and right use! ●

THE ECONOMIST POINT OF VIEW

by Frédéric Bizard

“We must stop focusing on a strategy to access care (a policy in which we were quite successful, as every French person has a health specialist near his home); we must now build a strategy to access health.

And if we want to implement this policy which is vital to maintain individuals in good health, we must develop selfcare and enable the French people to become more autonomous in dealing with their health. This approach obviously requires that people serenely make responsible self-medication their personal practice.”

What is self-medication medicine?

Medicine which is sold for self-medication use must comply with precise rules regarding composition (suitable active substance) and safety of use which will enable it to obtain a marketing authorisation (AMM, Autorisation de mise sur le marché) from the authorities. **This medicine, which is over-the-counter and not reimbursed, is therefore real, "genuine" medicine.**

Its efficiency and safety in normal use conditions are assessed and closely monitored throughout its commercialisation life-cycle. ●



PRECONCEIVED IDEA N° 2

"If a medicine is not reimbursed... it is necessarily not efficient!"

Reimbursement has nothing to do with the value and quality of a medicine: these are determined only by the award of a marketing authorisation (AMM) resulting from the assessment of its benefit-risk ratio.

11

Why selfcare must necessarily become the first step of the health care process regarding benign pathologies...

Although it is difficult to find a French equivalent for the word selfcare - the options "self-cure", "self-management of care" and "self-responsibility in care" didn't catch on - the practice itself is perfectly understood and integrated by the French people.

Selfcare has profoundly modified the relationship between patients, doctors and care. It started in the seventies with the fight to make medical practice more human and to increase autonomy regarding care and the choice of treatments³.

The patient has progressively positioned himself as an active player of his own health care process. His way of apprehending his own health has evolved: it has become a capital to preserve, obviously with the help of doctors in case of se-

vere pathologies, but also autonomously for minor ailments. This approach and new behaviour have been accompanied by access to over-the-counter self-medication medicine in pharmacies.

→ **Today, as a continuation of this evolution of society in its way of dealing with health, selfcare naturally tends to become the first step of the health care process for benign pathologies: this is the model Afipa defends. ●**

03.

SELF CARE: A STRATEGIC ASSET YET TO REORGANISE THE HEALTH CARE CHAIN

Selfcare: for an optimised reorganisation of the health care chain.

“ When you call to make an appointment and you are told that the doctor doesn't take any more patients, it's not normal ! Last time, I wasn't feeling well, I thought I had the flu, I was sent directly to emergencies.

After an hour and a half wait, I was told I would not be taken care of, because it wasn't an emergency! It's unacceptable! ”

Sophie's Mum
(who is never short of contradictions.)

Selfcare which includes responsible self-medication gives a new meaning to the health care process by enabling GP's and emergency doctors to focus on serious to severe pathologies, while pharmacists focus on minor ailments. This will not hamper the work of health care professionals, on the contrary, they will be able to work in better conditions: **not all of the 236 million consultations⁴ necessitate a medical opinion as first-line treatment.**

How many of these consultations could, if they were re-oriented, allow for better follow-up of patients with severe conditions?

Saturation of the health care chain: patient associations sound the alarm!

According to a survey published in October 2015⁵ by the CISS (Collectif interassociatif sur la santé), an inter-association group gathering 42 patient associations, **55% of the French people** (of which 64% belong to the working population) **have already experienced difficulties to obtain an appointment with a specialist in a reasonable timeframe** and 30% have already been told that a doctor refused to take on "new" patients. When confronted with this obstacle to care: although 28% insist and try to find another doctor, 20% of the French admit they go to emergencies.

These recent numbers illustrate a reality we all see every day: 28%⁶ of the consultations in emergency wards are due to patients not being able to see a GP quickly enough due to lack of GP availability – **the health care chain is saturated.**

An alarming situation which will not get any better: 58 104 GP's are working in private or dual practice in our country, that's **10.3% less than in 2007⁷** and the 2015 Atlas of the National Council of the College of Physicians (Conseil National de l'Ordre des Médecins) estimates there will be **only 54 000 GP's left in 2020.** ●

More and more chronic diseases, less and less time to devote to them...

Many GP's deal with a "just-in-time" activity and **with up to 150 consultations per week, with time spent on each patient sometimes as short as 10 minutes⁸**.

When 15 million of the French people⁹ suffer from a chronic disease necessitating complex care – a number which is likely to increase due to medical progress and longer life expectancy – 10 minutes are rather short, and represent a real public health issue.

The doctors themselves admit: **on average, 16 out of 100 patients seen in consultation suffer from a problem which could be solved with responsible self-medication, without involving a GP!** ●

Selfcare: give power to the patients to de-saturate the health care chain!

In this saturated situation, selfcare is the tool enabling each player fulfill his role in the health care system: the pharmacist is the proximity health care professional and the most appropriate contact for benign symptoms, the GP deals with more serious pathologies and emergency wards manage the most severe cases.

➔ **The development of selfcare could therefore regulate the health care offer by improving access to GP's and limiting congestion in emergency wards.** ●

THE ECONOMIST POINT OF VIEW

by Frédéric Bizard

“**A seventy-year-old person today has a much better health condition than a seventy-year-old person of the previous generation, and that's fine, just remember that in the fifties, people were retired during 5 to 7 years, against 23 to 27 years nowadays!**

But that means we have moved from short-term to long-term risk and that it will soon no longer be possible to finance all chronic pathologies resulting from such longevity for everyone, with the same quality of care and innovative products. If we want old age to be good news, if we want there

to be a controlled impact on the health care system, it is essential that we postpone illness for as long as possible in order to better manage the demand for curative health care.

This is the approach that will permit the allocation of funds to investment in innovation, and it is vital, because innovation is what will provide solutions to make this long-term care sustainable, it will also enable us, one day, to cure these diseases, or even act before they set in.”



Selfcare:
a gesture for the community...
but over and above all,
for my own health!

PRECONCEIVED IDEA N° 3

"Convincing all French people to pay for the medicine for their minor ailments, in order to preserve the common good, is quite a high challenge."

Selfcare is not only a responsible behaviour benefitting the community, it is also an investment for oneself!

Selfcare starts with "self": by preventing minor ailments thanks to a healthy lifestyle and treating them with self-medication medicine, the patient enables the health care system to finance other care... which he himself might need one day in case he develops a severe pathology or long-term health condition. When informing the French people of this reality, telling them that selfcare is the first step of the health care process is no challenge at all!

For that matter, 60% have already stated that they were willing to finance their own care for their benign pathologies².

**Selfcare : give power to the patients
to de-saturate the health care chain!**

“ *Do I mind paying for my cold medicine? Seriously, it cost me the same as 2 cups of coffee... Not much to pay for my peace of mind: look at what happens in other countries...*

We are lucky to have 100% coverage for our severe diseases and I want it to stay that way!

I'll be glad not to have to borrow money if one day I need extensive care... Do you have any idea of how much a chemotherapy costs Social Security? Find out, really, it's an eye-opener.”

Sophie to Aurélie

(who had never seen things under that angle).

**Selfcare: a gesture for the community... but over
and above all, for my own health!**

Financing health care is the second cause of worry for 83% of the French people, immediately behind financing retirement pensions¹¹. In these conditions, who could believe that they are not ready to consider favourably any proposal aiming to consolidate our solidarity-based health care system?

Selfcare is this solid proposal, able to convince our compatriots and calm their worries, because it is both a remarkable **sustainability tool for our current health care system** and the guarantee of an **individual return on investment for each French person**. In this way, it is without doubt the best existing pedagogical tool to gradually raise awareness on the necessity for evolution of our consumer behaviour regarding “health care goods” towards increased responsibility... to benefit each and every one of us.

One must therefore consider selfcare as a solidarity-based behaviour, in the true meaning of the word; solidarity being the relationship between people who, because they share a common interest, are interlinked...

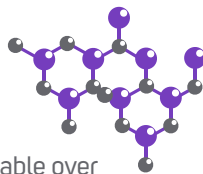
➔ **Sharing a common interest is key: by avoiding disease and treating one's minor ailments without going through the consultation, prescription and reimbursement process, the patient makes the health care system sustainable so that he can finance his neighbour's long-term health condition as well as his own! ●**

04.

THE ECONOMIC CHALLENGE OF SELF-MEDICATION IN FRANCE: OVER 1,5 BILLION EURO SAVINGS IN ONE YEAR ARE AT STAKE!

France is lagging behind while Europe is developing selfcare!

90
molecules



could become available over the counter if France were aligned with neighbouring European countries¹².

16

Self-medication is much less developed in France than in other countries: **its volume represents only 15.4% of the French market versus 32.3% on average in the European countries** observed: Germany, Belgium, the Netherlands, Spain, Italy, Sweden and the United Kingdom.

Yet, when compared with the situation in other European countries, selfcare in France has major development: **90 molecules could become available over-the-counter if France were aligned with its neighbouring European countries.** This discrepancy between France and the rest of Europe illustrates the inadequacy of the French system which does not accompany the evolution of our society and the ever-increasing demand of the French people to take more control over their health care.

PRECONCEIVED IDEA N° 4

"The French people will never all accept to pay even 5 euros per month for their self-medication medicine!"

When French people are asked to indicate the maximum amount they are willing to pay for over-the-counter, non-reimbursed medicine recommended by their pharmacist to take care of a benign health issue (a cold, sore throat, runny nose, dry cough, fever...), **they answer 11 euros² !**

Reminder: the average price of self-medication medicine is 4.69 euros¹⁶.

In addition, over 7 French people out of 10² indicate that non-reimbursement does not prevent them from purchasing over-the-counter medicine

→ Yet such a change is not only possible, it is indispensable! ●

The self-medication market in France: we've got everything to succeed... except willpower!

What prevents the development of self-medication in France

The detrimental confusion between efficiency and reimbursement and the lack of political drive to develop the offer of self-medication medicines (switch) constitute well-identified blocking factors. This is evidenced by the fact that **only one national switch took place between 2012 and 2014, versus six in 2010.**

Indeed, although self-medication medicine is financially accessible, the French system continues to favour the "all-doctor" approach and the financial coverage of minor ailments by the community. An approach which disregards both the necessities of the current socio-economic context and the evolution of patients who are prepared to change their practice if they are given reliable, accessible and varied means to maintain their good health and treat their benign health issues.

→ **In order to respond to the French demand and fully express its economic potential, the French self-medication market must be supported by strong political drive and concrete measures. This price is calculated on optional medical prescription medicine, reimbursable and non-reimbursable.** ●

- ✓ Over 1,5 billion euro savings per year can be generated by developing self-medication in France.
- ✓ Only one national switch between 2012 and 2014 versus 6 in 2010.
- ✓ The self-medication market has been unstable for several years now: -3% in 2013, -0.3% in 2014 and +5.2% in 2015 (volume data). The reason is that, due to the lack of in-depth reform, the self-medication market evolves according to events: in other words, whenever pathologies appear.

THE ECONOMIST POINT OF VIEW

by Frédéric Bizard

“ The price of such medicine is low (an average of 4,69 euros), and individual, responsible self-medication costs no more than 5 euros per month. This means that a majority of the population can easily bear the cost. Of course, the specific cases must be dealt with separately, but one should not focus policy on extremes.

The possible price discrepancies between different areas are naturally absorbed by very efficient

competition, which easily occurs as 22 192 pharmacies are present in the country.

Arguing that the price would be too heavy a burden for the French people is therefore irrelevant and demonstrates a total lack of understanding of the situation and of what selfcare represents: it is the major factor able to give public finance, and the Public Health Insurance, the leeway necessary to finance real innovation for all... including the most disadvantaged members of the population! ”

And yet, substantial savings exceeding 1,5 billion euros could be generated and reallocated to more efficient use¹⁷...

Financial coverage of health care costs: a model to re-think...

A reform of the way health care costs are covered must be implemented today, and pathology is the starting point.

Pathologies which are considered severe must be covered collectively. The medicine used to treat these pathologies must therefore be reimbursed.

At the same time, the cost of benign pathologies must be borne individually. **A list of these benign pathologies has been proposed by Afipa, based, in particular, on the list defined by the French Health Products Safety Agency (Agence nationale de sécurité du médicament et des produits de santé¹³ - ANSM).** A few examples: occasional adult constipation, dry and irritation cough. All the molecules which treat these benign pathologies must no longer be financed collectively.

In parallel, the offer of self-medication medicine must be extended to all benign pathologies. As a result, the medicine used to treat these pathologies will become available over-the-counter and will no longer be reimbursed.

On the other hand, certain medicines for which the cost is not currently covered collectively may become reimbursed, if the pathology they correspond to is identified as requiring collective coverage. ●

... in order to maintain a health care system based on solidarity

The model proposed here would result in major savings exceeding **1,5 billion euros in only one year¹⁷.**

These savings are based on both the extension of the offer of self-medication medicines (switch) and a reform of the financing. This number takes into account the savings on medical consultations and the reimbursement of medicines by the Public Health insurance. It is a minimum estimate which does not include the savings on indirect costs, related or unrelated to dealing with a disease: for example, sick leave and lower productivity at work.

As you can see, the development of self-medication in France is an efficient solution to reduce the deficit of our health care system, in the same way as generic medicine.

These savings, even when taking into account the lowest estimates, would already contribute to preserving the solidarity-based financing of severe/long-term pathologies while reinforcing – and that's the most remarkable point – the right of the French people to take care of their own health, by giving them increased freedom without sacrificing their safety. ●

THE ECONOMIST POINT OF VIEW

by Frédéric Bizard

“Selfcare is “empowerment” accessible to all. There is no financial obstacle to selfcare; politicians have greatly underestimated its impact on both maintaining individuals in good health and providing an efficient system, which constitute the essential strategic levers to sustain our health care system.

Selfcare is decisive because it is the best way to move from our old system to a new one, gathering all existing players, which is key to make a reform project politically defensible and realistic. Today,

selfcare spendings per person in France are lower than in most countries, whereas French spendings on non-selfcare medicine are higher than the average in OECD countries.

If today we want to implement this policy, which is indispensable to maintain individuals in good health and which provides efficient health care, we must urgently develop selfcare.”

05. HOW WE CAN DEVELOP SELF-MEDICATION IN FRANCE

1

Reform the rules of financial coverage and develop the self-medication medicine offer.

- ✓ **List the benign pathologies considered as self-medicable.**
- ✓ **All molecules associated with these self-medication pathologies may be available without medical prescription.**
- ✓ **All molecules associated with these self-medication pathologies must be switched**, i.e. removed from the mandatory medical prescription list.

2

Associate the health care professionals and the patients throughout the groundwork approach.

- ✓ **Organise a large-scale conference on responsible self-medication, gathering all health care professionals** in order to involve them in the reflection process and provide them with tools to support them in their daily practice, in particular :

- Provide decision trees in order to facilitate the delivery of medicine over the counter. Define a protocol for pharmacist advice throughout the country.
- Indicate self-medication medicine on the pharmaceutical and medical records, avoid any individual misuse.
- Implement specific in-service training programmes regarding self-medication advice over-the-counter.
- Set up a yearly GP consultation focused on self-medication.

- ✓ **Prepare the future health care professionals**, increase the knowledge of in-service pharmacists by giving them the option to deliver certain products, provided they validate specific training programmes.

- ✓ **Inform the French people about responsible self-medication** by reinforcing health education via an information campaign which could be delivered by the French National Institute for Prevention and Health Education (Institut national de prévention et d'éducation pour la santé, INPES), and by implementing dedicated educational programmes.

3

Facilitate self-medication and ensure it is financially accessible in order to obtain patient support.

- ✓ **With an appropriate VAT rate:**

Apply the same VAT rate (2.1%) as for prescription medicine, due to the fact that self-medication medicine must comply with the same marketing regulations and offer the same safety guarantee.

- ✓ **By including self-medication in the universal illness coverage (CMU, couverture maladie universelle):**

Include self-medication in the free and/or supported social protection system, i.e. the universal illness coverage and its complement (CMU-C, CMU complémentaire) and the additional support for a complementary health care insurance (ACS Aide à la Complémentaire Santé). The objective is to provide free self-medication medicine to people with limited financial means



06. CONCLUSION

Our health care system, although remarkable, suffers from an ever-increasing deficit, and its sustainability is threatened by sociological challenges it is unable to meet.

Yet resources exist, they are reachable and ready to be deployed; they will enable the system to adapt and increase its efficiency. One of those remarkable resources is selfcare and, more precisely, self-medication, which has proven its efficiency in neighbouring European countries, where it has rationalised the health care process and generated substantial savings while responding to patient expectations.

In France, everything is ready to increase the development of selfcare rapidly: the patients, pharmacists, medicine industries, distribution and control networks... even the GP's are gradually joining this trend.

Today, the only missing factor is a strong political willpower to place selfcare at the heart of a new health care strategy, focused on the individual. This is both surprising and unfortunate, as we know that promoting selfcare means we can provide a documented, solid, efficient and federating response to the organisation and financing issues of our healthcare system.

→ **Afipa and its members are willing to share their expertise and support any political action aiming to develop selfcare in France.**

Thanks to this approach, we will create the foundations of a sustainable, reformed health care system able to mirror the evolution of our population, meet new health challenges and take into account economic constraints. ●



Today, we at Afipa consider that, in view of the financial constraints jeopardising our health care and our system's much needed but challenging reorganisation, it is our duty and our responsibility to draw the attention of the public authorities to the absolute necessity of making optimum use of the strategic asset represented by the development of selfcare in France.



AFIPA

Afipa gathers 37 member pharmaceutical companies representing 60% of the selfcare market and 80% of the self-medication sector in France¹⁴.

Pascal **BROSSARD**
President

Antoine **BON**
Vice-President

Éric **MAILLARD**
Vice-President

Philippe **BOYER**

Anabelle **FLORY-BOIRON**

Enrique **GANEM**

Evangelos **GEORGAKOPOULOS**

Dominique **GIULINI**

Stéphane **GRENON**

Pascal **LEFRANÇOIS**

Benoit **VAN DER WOLF**

Julien **ZELLER**

Daphné **LECOMTE-SOMAGGIO**
Managing Director

07. GLOSSARY

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AMM: marketing authorisation (AMM, Autorisation de mise sur le marché): authorisation given to a titulaire (generally a pharmaceutical company) enabling him to commercialise a given medicine. This autorisation is delivered by the ANSM or by the European Commission for certain medicines (in particular, innovative or orphan). This authorisation is valid 5 years.

...

Benefit/risk ration: a sssessment of the therapeutic benefits compared to the safety risks related to the use of a given medicinee.

...

De-reimbursement: decision by the Minister of Health, upon recommendation by the Transparency Commission of the High Council of Health (Haute Autorité de Santé, HAS), not to reimburse a given medicine.

...

Family or officinal medication: medicine available in an open access area within a pharmacy.

...

List: the Public Health Code in France supervises a list system (list I, II, narcotics) on which the active ingredients may be indicated. The medicines on lists I and II require medical prescription.

...

Mandatory medical prescription: a pharmacist may provide a patient with medicine under this status only if he or she is presented with a medical prescription.

...

Medicament - medecine: a medicine is a product used to treat or prevent a disease, or reduce its symptoms. It may also be a diagnosis tool. It is composed of one or several active substances and excipients.

...

Misuse: an intentional, inappropriate use of a medicine or product, non-compliant with the marketing authorisation or registration, or best practice recommendations.

...

Open access: measure implemented on July 1st, 2008, enabling pharmacists to provide their patients with optional medical prescription medicines, listed by ANSM, within a dedicated area, clearly identified and near the counter in their pharmacies.

...

Optional Medical Prescription: medicine which a pharmacist is authorised to deliver without a medical prescription.

...

OTC medicine: over-the-counter medicine sold in pharmacies, in open access areas and not reimbursed.

...

Personal medical record: computer tool listing the medicines delivered to a patient over the past four months. The pharmaceutical record was created by the law of January 30th, 2007, relating to the organization of certain health care professions.

...

Pharmaceutical record: computer tool which, on patient request, lists the medicines delivered to him or her over the past four months.

...

Pharmacovigilance: the purpose of pharmacovigilance is to monitor, assess and prevent the risk of adverse reaction caused by the use of medicines and products for human use. It ensures that medicine is used in compliance with the terms of its marketing authorisation.

It covers :

- Reporting adverse reactions and gathering related information.
- Listing, assessing, processing this information for prevention use.
- Conducting surveys or analyses regarding the safety of use of medicines.
- Implementing actions: modification of the information delivered to health care professionals and patients, suspension, withdrawal of the marketing authorisation.

...

Prescription and delivery conditions: the prescription and delivery conditions define the patient's access to medicine. The prescription and/or delivery of a given medicine may be restricted, i.e. for exclusive use by hospitals or certain doctors, or subject to certain conditions (duration of treatment, complementary tests), in the interest of patients.

...

Reimbursement: decision by the Minister of Health, upon recommendation by the Transparency Commission of the High Council of Health (Haute Autorité de Santé, HAS), following a request by a pharmaceutical company to have a given medicine reimbursed.

...

Responsible self-medication: responsible self-medication is the possibility for individuals to deal with their illness by taking self-medication medicine which is authorised, over-the-counter, safe and efficient in the use conditions indicated, with pharmacist advice (source: World Health Organization year 2000).

...

Selfcare: English word used when an individual manages his own health care, and which covers in particular the concept of responsible self-medication.

...

Switch: regulatory procedure by which a pharmaceutical company requests the medicine registration authorities to remove an active substance (a molecule) from the list of mandatory prescription medicines. As a result, this medicine becomes available over-the-counter

...

Therapeutic indication : the therapeutic indication provides information on the disease or symptoms which the medicine is able to treat or prevent, or on the diagnosis it contributes to determine. The indication is included on the marketing authorisation (AMM).

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