

## CHANGE OF LEVOTHYROX (EUTHYROX / EUTIROX) FORMULA IN FRANCE

### WARNING FOR PATIENTS FROM OTHER EUROPEAN COUNTRIES

A major health crisis has been under way in France since spring 2017, following the introduction of a new formulation of Merck's *Levothyrox*. This new formulation replaces the old formulation manufactured under the same name, but on the basis of a new patent with modified excipients. In other European countries, this drug is known as *Euthyrox* or *Eutirox*. Up to now, the formulation has only been changed in France, but the manufacturer has announced that it plans to introduce this new formulation throughout Europe by the end of 2018.

The new *Levothyrox* was put on the market in the following circumstances:

- Study of bioequivalence on healthy volunteers, but with **no switch study** on patients with a real thyroid condition;
- **Inadequate and insufficient information** to health professionals and patients, indicating that there were "no expected effects";
- **Monopoly** situation of Merck's *Levothyrox* on the French market for levothyroxine sales (99% in 2017); and
- **Inertia of public authorities** which led a delayed and inadequate reaction to this health crisis which is still unresolved.

At the end of November 2017, an **unprecedented number of pharmacovigilance reports** had been registered and this number is still increasing. A survey by health authorities showed that reported adverse effects were linked (i) in 10% of cases, to a transition to hyperthyroidism; (ii) in 23% of cases, to a transition to hypothyroidism; and, most importantly, (iii) **in 67% of cases, to no known cause**. A scientific study is to be carried out shortly with the assistance of health authorities, and analyses are in progress. For now, no one has any explanation as to what causes these undesirable effects without affecting thyroid imbalance. This situation is extremely worrying.

In this context, almost **one million patients** of the three million patients in France who were prescribed *Levothyrox* have shifted to other drugs despite great difficulties in getting access to alternatives. The lack of anticipation and reactions from health authorities has resulted in **great distress for patients**, and also for health professionals.

**The manufacturer is planning to distribute the new formulation throughout Europe by the end of 2018** (under the same name as before: *Euthyrox* / *Eutirox*). It is for this reason that we are drawing your attention to this situation today. The European Medicines Agency (EMA) has given a green light, despite our warnings which have not been relayed by the French Government.

Patients in other European countries are relatively lucky not to be in a monopoly market like France. However, all **patients using *Euthyrox* or *Eutirox* from Merck run the same risks as we do**.

On the basis of what we have experienced in recent months, and given the many outstanding questions, please read carefully below our attention points and recommendations:

- Advise, and **forward your concerns to, health authorities** in your country, as well as to the **EMA**;
- **Require that switch studies on actual patients are performed** before the new formulation is introduced in your country (pending conclusions of the procedures and studies underway in France);
- **Inform patients** who are currently on *Euthyrox* / *Euthyrox* from Merck; and
- Make every effort to ensure that the most fragile or **at-risk patients** (ie., cancer patients, pregnant women, cardiovascular diseases, etc.) are **carefully monitored** on a biological level or are offered the opportunity to switch to other drugs early (*likewise any patient at all, for the sake of risk prevention*).

We are at your disposal to answer any of your questions.

**Contact : [Investig.action.levo@gmail.com](mailto:Investig.action.levo@gmail.com)**

Association française des malades de la thyroïde (AFMT) : [asso.thyroide@gmail.com](mailto:asso.thyroide@gmail.com)

Vivre sans Thyroïde (VST) : [info@forum-thyroide.net](mailto:info@forum-thyroide.net)

April 11<sup>th</sup>, 2018

## **CHANGE OF MERCK'S LEVOTHYROX (EUTHYROX / EUTIROX) FORMULA IN FRANCE: WARNING FOR PATIENTS FROM OTHER EUROPEAN COUNTRIES**

Dear friends,

We wish to inform you about a **major health crisis** related to the introduction of Merck's new *Levothyrox* formula (known as Euthyrox or Eutirox in other European countries) on the French market, in March 2017. According to the manufacturer, this new formula is planned to be **marketed throughout Europe by the end of 2018**.

Following the filing of 7,000 complaints in France concerning this new formula, the health division of the Regional Court (*Tribunal de Grande Instance*) of MARSEILLE opened a judicial investigation on March 2<sup>nd</sup>, 2018 *against person unknown* for aggravated deception, involuntary injury and reckless endangerment. Thousands of civil claims have also been filed for lack of information.

According to French health authorities, **more than 500,000 people** have abandoned the new *Levothyrox* formula for alternative levothyroxine-based drugs (a number officially admitted by our Ministry of Health this week). But the association of patients "Vivre sans Thyroïde" ("Living without a thyroid"), which analyzed the official data made public by the National Health Insurance Fund, believes this number - although impressive - is still an underestimate, as it could increase to **one million people (or one in three patients)** after taking into account patients who purchase the old formula abroad (and thus do not appear in the health insurance data) as well as large numbers of *Levothyrox* new formula issued in duplicate with alternatives in the last quarter of 2017 and that patients therefore did not use. (*Please refer to links (1) and (2) at the end of this letter*)

How did we get here? Here is the background to this crisis:

Since *Levothyrox* was in a **monopoly** situation in France at the time of introduction of the new formula, there was no available alternative for patients suffering from hypothyroidism or having undergone thyroidectomy.

According to official information, this change of formula was a result of a request by the National Health and Drugs Agency (ANSM) to Merck in 2012, under the pretext of a lack of stability of the old formula (*the patent of which will expire in 2019*). The patent for the new formula was filed in 2014. The manufacturer replaced the lactose excipient with mannitol and citric acid. There have been no clinical trials, only a "bioequivalence study" performed on 200 healthy individuals to test the absorption over 72 hours, which does not allow the evaluation of side effects or tolerance of *Levothyrox's* new formula in the long term, on real patients.

*Levothyrox's* old formula was used by **three million patients in France**. Even assuming that the change in formula would only affect a small percentage of these patients, a relatively large number of patients with intolerances and side effects should have been anticipated. Similar problems had already occurred in other countries (Denmark, Israel, New Zealand) during changes in formulae of other levothyroxine-based drugs, as **these drugs have a narrow therapeutic margin**. The minimum would have been to warn patients and doctors, and to advise them to monitor patients changing to the new formula carefully. **However, very little information was provided, and it was incomplete and inaccurate.**

A large number of patients experienced **side effects, sometimes of which were very disabling** (weakness and lack of energy, muscle and joint pain, digestive disorders, serious cardiac disorders, hair loss, insomnia, vertigo, depression, weight gain, balance disorders, memory loss, etc.) without understanding why, and often without being listened to by their doctor who had been assured in an official letter that "no change is expected for patients".

From September 2017 onwards, in an urgent reaction to the crisis, Merck started to train its medical representatives to inform doctors about its new products.

However, it was revealed that as early as July 10, 2015, nearly two years before the launch of the new formula, the need to "organize **levels of adaptation for at-risk populations**" had already been underlined during a meeting at the ANSM with Merck's officials.

Among the patients considered as "at risk" are those with cancer or cardiovascular disorders, pregnant women, children and elderly people. However, these patients were not protected by our authorities, since they were forced to switch to the new formula along with other patients, with the only recommendation being to monitor them a little more carefully.

As of November 30, there were more than **17,000 documented reports** about side effects on the government's "pharmacovigilance" portal. However, only a small percentage of the affected patients reported side effects as the process is relatively complicated.

Faced with this dramatic situation, the reaction of Merck and the French health authorities was based on **denial, and even contempt**. Mrs. Agnès BUZYN, the French Minister of Health, did not launch any investigation of the State services. A patient association, the AFMT, funded an independent analysis of the quality of the new formula, the results of which have not yet been reported. The association Vivre sans Thyroïde, for its part, assigned Merck to an expert referral in order to request the communication of various information and an independent pharmaco-toxicological analysis of the new formula.

Given the extent of adverse effects and the failure of many health professionals to listen to patients, patients helped each other on social networks, and purchased the old Levothyrox formula abroad (up to now, the formula has only been changed in France) at their own expense. French authorities and some medical professors have even invoked a **nocebo effect**, or a **collective hysteria**, attributing the crisis to the media attention.

During the autumn of 2017, following a petition signed by more than 300,000 people, the mobilization of many patients, and exchanges with several patient associations, the Ministry of Health urgently made a small stock of the old formula available and opened the market to alternatives (which were difficult to find or insufficient in French pharmacies for many months, and without knowing if they would be suitable for the patients). The most important issue in this scandal is that at no time was the possibility of producing the old formula again for patients who had been well balanced with this treatment for many years, sometimes decades, an option.

Merck reportedly responded to a request from the ANSM in 2012 to justify the change of the formula. But the argument of insufficient stability of the old Levothyrox formula is not valid if we consider the study of bioequivalence made by Merck which demonstrates a perfect bioequivalence between the two formulas over a period of 18 months, which is the shelf life of the new formula.

**What are the true reasons for this change of formula?** Is it the fact that the patent of the old formula will soon expire? Or is it the desire of the laboratory to conquer Asian markets where lactose intolerance is much more common than in Europe and where Merck has just built a gigantic plant?

**Merck has planned to distribute its new formula in all European countries by the end of 2018, while permanently excluding a return to the old one.**

**However, ANSM's pharmacovigilance survey**, based on the more than 17,000 reports received, published on January 30, 2018, leaves many questions unanswered: why did two thirds of the patients concerned have adverse effects with a TSH that remains within the reference range? Why do these patients often report conflicting symptoms (hypo- and hyperthyroidism) at the same time? Why, in in two thirds of patients, do the symptoms improve, often within a few days, as soon as they return to the old formula or switch to another brand?

The symptoms currently experienced by patients should be the starting point for studies to discover the causes and to propose therapeutic solutions. This is the essence of medical reasoning. The ANSM and the French Directorate General for Health (DGS) turn their backs on it with a plan to undertake a cross-over experiment, too limited in number, duration and power compared to the variety of symptoms, and all the more useless since it has already been performed on nearly three million patients. *(Please refer to link (3))*

However, ANSM's Vice-President, Mr. Claude PIGEMENT insists: "a precise scientific study of what happened with this drug is necessary". *(Please refer to link (4))*

In this context, it seems obvious that it would be premature to introduce the new formula in other countries.

We alert European patients using Euthyrox / Eutirox on the need to express your determination not to undergo a forced change of formula, as long as neither the health authorities nor the manufacturer can prove the real need or determine the reasons for so many side effects experienced by so many French patients. People at special risk (i.e., those with cancer or heart disease, pregnant women, children, and the elderly) should consider switching to an alternative as long as this is feasible without any pressure. Special caution is needed for pregnant women who must absolutely avoid taking the new formula of Euthyrox / Eutirox until the toxicological aspects have been clarified.

We further invite you to write to the Health Agency of your country as well as to your Ministry of Health, to the European Medicines Agency (EMA) and to the President of the European Commission to inform them of your opposition to such a change.

We will of course keep you informed of the evolution of this health crisis of which of you may, like us, become victims.

Yours sincerely,

*On behalf of the French thyroid patients*

Contact : [Investig.action.levo@gmail.com](mailto:Investig.action.levo@gmail.com)

**Signatories of the letter :**

Association Française des Malades de la Thyroïde (AFMT) - <http://www.asso-malades-thyroïde.fr>

Vivre sans Thyroïde (VST) - <https://www.forum-thyroïde.net>

## ***FRENCH THYROID GROUPS SIGNATORIES :***

- **AFMT- Association Française des Malades de la Thyroïde**
- **VST- Association Vivre Sans Thyroïde**
- **VNLO Collectif des Victimes du Nouveau Levothyrox en Occitanie**
- Agir pour le retour de l'ancienne formule levothyrox (2609 membres)
- Collectif 05 contre le nouveau Levothyrox (78 membres)
- Collectif Champagne Ardenne VNLO (125 membres)
- Collectif Grand Est des malades du lévothyrox NF (117 membres)
- Collectif Levothyrox 47 (47 membres)
- Collectif Papillons libres Rhône Alpes Auvergne (339 membres)
- Collectif Thyroïde Plainte Levothyrox 44 / 49 / 85 (45 membres)
- Collectif Victimes Levo Reims Grand Est (117 membres)
- Détresse Thyroïde (41 membres)
- Groupe Collectif des Victimes du Nouveau Levothyrox Nièvre (58 membres)
- Groupe de Parole sur le levothyrox (département 33) (523 membres)
- Hashimoto, Basedow et autres maladies de la thyroïde (2734 membres)
- Hypo-Hashi-Hyper-basedow (3603 membres)
- Le Levothyrox 21 Groupe de parole et d'échange (94 membres)
- Les Papillons du 17 (effet indésirable de la NF du levothyrox) (45 membres)
- Levo NF Breizh (Bretagne) (432 membres)
- Levo NF Île de France (45 membres)
- Levo Tous pour une plainte (406 membres)
- Levothyrox départements 44 & 85 (158 membres)
- Levothyrox et thyroïde 66 et au-delà ... (158 membres)
- Levothyrox nouveau Hérault 34 (27 membres)
- Levothyrox nouvelle formule - groupe du 62-59 (214 membres)
- Levothyrox nouvelle formule - Thyroïde (16 267 membres)
- Levothyrox nouvelle formule - collectif Île de de France (91 membres)
- Levothyrox nouvelle formule - Effets secondaires (3009 membres)
- Levothyrox nouvelle Formule , Parlons-en (366)
- Levothyrox nouvelle formule Thyroïde Arnaque (3112 membres)
- Levothyrox Paca (258 membres)
- Levothyrox Rhône-Alpes Auvergne (01/03/07/15/26/38/42/43/63/69/73/74) (342 membres)
- Liberthyrox (73 membres)
- Problèmes de Thyroïde, groupe d'échanges (14 653 membres)
- Problèmes de Thyroïde, Hypothyroïdie (12 561 membres)
- Qui veut le retour de l'ancienne formule du Levothyrox ? (2200 membres)
- SOS Thyroïde Corse - Tous en marche pour notre santé (529 membres)
- Thyroïde Région parisienne (335 membres)
- Thyroïde - Infos (2999 membres)
- Union des Papillons libres (986 membres)
- Victimes du nouveau levothyrox 65 (44 membres)
- Victimes du nouveau levothyrox du 34 (42 membres)
- Victimes du nouveau levothyrox en Alsace (331 membres)
- Vivre sans thyroïde FB (5156 membres)
- Vivre sans thyroïde on en parle ici (7102 membres)

## Translation

# “New LEVOTHYROX FORMULA: a “totally unexpected frequency” of reporting of adverse reactions

1 February 2018

By Jean-Philippe Rivière, VIDAL.fr

[https://www.vidal.fr/actualites/22566/nouvelle\\_formule\\_de\\_levothyrox\\_nombre\\_totalement\\_inattendu\\_de\\_signalements\\_d\\_effets\\_indesirables/](https://www.vidal.fr/actualites/22566/nouvelle_formule_de_levothyrox_nombre_totalement_inattendu_de_signalements_d_effets_indesirables/)

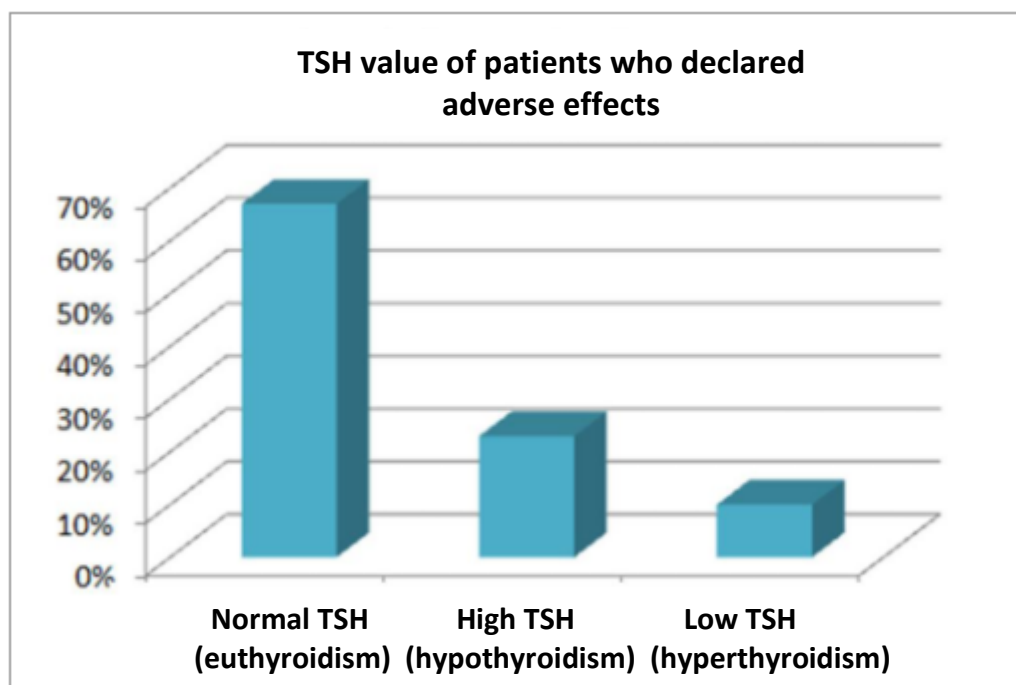
The national pharmacovigilance survey of the ANSM (the French National Agency for Medicines and Health Products Safety) [published on 30 January 2018](#) shows a **"totally unexpected frequency of reporting"** of adverse reactions with the new formula of LEVOTHYROX. Moreover, in **2/3 of the cases, they occur without biological thyroid imbalance** (when adequate follow-up of TSH has been carried out).

It should also be noted that the **peak of declarations of symptoms was in June/July 2017** – before the media crisis following testimonies of associations or leading figures in the media, which **relativizes the argument advanced by the ANSM of an "amplifying effect due to the new reporting portal and social networks"** (and which also relativizes, even invalidates, the hypothesis of a *nocebo* effect).

Moreover, according to the authors of this report, **these adverse reactions are not new, specific to this new formula**. But **no explanation is advanced** to explain these adverse effects, mixing signs of hypo and hyperthyroidism with normal or disturbed blood test values.

In order to further explore the consequences of this change in formula and the subsequent arrival of other levothyroxine-based drugs, the ANSM will conduct further investigations, particularly from health insurance data (SNIIRAM data base).

For **Claude Pigement**, vice-president of the ANSM [interviewed on 30 January by \*Le Parisien\*](#), **the gap widens between medical elites and patients**. These investigations should thus also be completed by the **"publication of the entire pharmacovigilance report of 2012"** from which originates the change of formula (a report only available in a summarized format, which preoccupies the patient associations).



The TSH value was within the normal range for 67% of the patients taking the new LEVOTHYROX formula and submitting a declaration of adverse effects

## A pharmacovigilance report completing the report published in October 2017

The launch of the **new LEVOTHYROX formula in March 2017** was accompanied by the start of a **national pharmacovigilance survey by the ANSM**.

The first results of this survey (the "first survey") were published in October 2017. They in particular showed a **high frequency of reports** and the **occurrence of signs of hypo or hyperthyroidism in spite of TSH assays within the expected standards**, which intrigued the authors of the report ([see article \(in French\) on VIDAL.fr](#)).

The ANSM then published [on 30 January 2018](#) the additional data from the analysis of the declarations submitted between 15 September and 30 November 2017 (the "second survey").

## More than 17,000 reports of adverse effects to the authorities

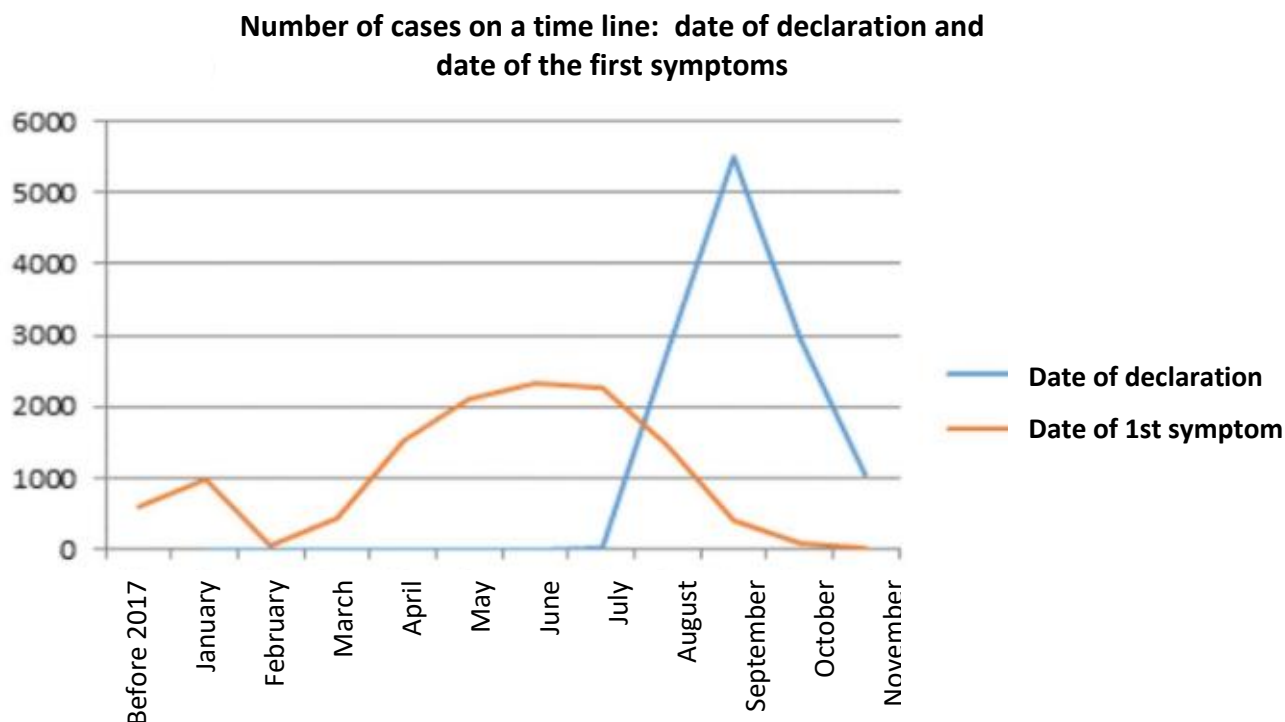
Reports of adverse effects from patients taking LEVOTHYROX registered in the national pharmacovigilance basis (via the [signalement-sante.gouv.fr](#) web portal) have amounted to **17,310 since March 2017** (0.75% of the 2.3 million users of the new formula): **5,062 during the first survey** (end of March – mid-September 2017) and **12,248 during the second survey** (mid-September – end of November 2017).

This high frequency was qualified by the authors of the report as "**unprecedented**" and "**totally unexpected**". It is also necessary to add some or all of the **18,000 reports made directly to Merck** since March 2017 (it is difficult to know whether these reports are duplicates, or not, of those made on [signalement-sante.gouv.fr](#)).

## A peak of symptoms that occurred before media coverage

The majority of these adverse reactions occurred **between April and September 2017**, with a **maximum in June and July**, which seems to reduce the role of media coverage, and therefore also excludes, at least partially, the potential role of a *nocebo effect* (perception of unusual symptoms as a result of rumors, media coverage of such symptoms, or simply by reading the package insert).

Nevertheless, the **entering date of these adverse events mainly occurred in September**, after the outbreak of the crisis, as summarized in this graph of the ANSM:





### On average, patients reported 5 adverse reactions

Patients reported an average of **5 adverse effects** (from 1 to 36). The majority were **women** (90.4%, knowing that this drug is also used mainly by women), the **average age was 55 years** ( $\pm$  13 years). The number of **pediatric cases** was 17.

### General, neuro-psychiatric, musculoskeletal symptoms: list of the most frequently reported adverse reactions

The adverse reactions reported to the authorities are **similar in the first survey and the second survey**, with an overall predominance (by order of frequency) of:

- **General symptoms:** fatigue (9.4% of all reports), asthenia (3%).
- **Nervous system disorders:** headaches (6.2%), migraine (1.1%), disturbance of attention (1.2%), amnesia (1.1%).
- **Psychiatric disorders:** insomnia (4.5%), sleep disturbance (1.2%), irritability (1.8%), depression (1.5%).
- **Musculoskeletal disorders:** Muscular contractures (4.2%), muscle aches (2.8%), joint pain (2.3%).
- **Gastrointestinal disorders:** nausea (2.4%), diarrhea (1.6%).
- **Alteration of clinical or biological measures:** weight gain (3%), increased TSH (1.7%).
- **Skin conditions:** Hair loss (4.7%), sweats (1.2%)
- **Ear ailments:** dizziness (5.5%), tinnitus (0.2%).
- **Cardiac disorders:** palpitations (1.8%), tachycardia (0.9%), arrhythmia (0.2%).
- **Visual disorders** (0.9%).
- **Respiratory ailments:** dyspnea (0.8%).

The **symptoms reported directly to Merck between March and late November are of the same order**, with a predominance of general, neuro-psychiatric and musculoskeletal symptoms.

### 19 cases of deaths were reported and analyzed, with no proven link to the new LEVOTHYROX formula

According to the ANSM, for the 19 deaths recorded in the pharmacovigilance database (dizziness and death at 85 years old, fetal death, acute respiratory failure, suicide, etc.), *"it is not possible to assess or to formally exclude a link with the taking of the new LEVOTHYROX formula"*.

### In 2/3 of the reports adequately documented, TSH level was normal

**1,745 reports of adverse reactions** included sufficiently documented biological analysis.

The analysis of these 1,745 reports shows that if symptoms are reported:

- **67%** (1,172 declarations) were associated with **normal TSH** (euthyroidism).
- **23%** (394 declarations) were associated with **high TSH** (hypothyroidism).
- **10%** (179 cases) were associated with **low TSH** (hyperthyroidism).

These proportions remain unchanged when the analysis is carried out by **age groups**, or according to **BMI** (*body mass index*).

**Symptoms are close, whether patients have low, normal, or high TSH**, although quite logically, the number of neuro-psychiatric and cardiac disorders appears to be somewhat higher in case of hyperthyroidism.

Likewise, **the distribution of biological results appears similar depending on the indication** for which LEVOTHYROX is used.

### Biological discordance – symptoms already seen before

The ANSM noted that a recent study has already revealed the **occurrence of abnormal symptoms under levothyroxine with normal TSH** ([Mc Millan et al. 2016](#)).

Another study ([Hennessey et al. 2010](#)) showed the **onset of symptoms of both hypo and hyperthyroidism in patients whose TSH varied**, following a change in formula (89%) or not (11%).

Other studies have attempted to analyze the link between changes in TSH and depressive symptoms, but with results that are difficult to interpret – different populations, ages, numbers, etc.

### **Recognition of the possible negative impact of some of these adverse effects**

The report on the pharmacovigilance survey stresses **"the weight of the 339 adverse effects considered as severe in terms of discomfort in daily life**, reported by patients (driving and walking in particular)."

### **The adverse effects in general occurred quickly, and in many cases disappeared when switching to another brand (which is possible since fall 2017)**

In one out of two cases, the adverse reactions appeared on average **within a period of less than 1 month after the transition to the new LEVOTHYROX formula**.

The **symptoms improved in 20% of cases**, "especially among those who switched to another brand", which "reinforces the importance of [progressively] providing therapeutic alternatives" since autumn 2017.

However, patients who have switched to another brand may have struggled to continue their treatment with the same alternative, due to **supply difficulties**.

### **"No satisfactory hypothesis to explain the occurrence of these effects"**

**At the end of their analysis, the authors of the report are perplexed**, unable to identify potential patients at risk or to formulate a satisfactory hypothesis to explain the occurrence of these non-specific adverse reactions, with or without TSH disturbance, evoking signs of hypo or hyperthyroidism.

Similarly, the authors **cannot identify a direct link between the onset of these symptoms and the composition** of this new LEVOTHYROX formula.

### **Nationwide study**

This survey of pharmacovigilance reports will be **completed by the studies carried out by the Epidemiology of health products department** of the ANSM based on the health insurance database (SNIIRAM), including a study of use and a study of risk.

### **For the vice-president of the ANSM, the gap is widening between the medical elite and the patients. So we have to go further to explain this phenomenon.**

As we have seen, a **significant number of adverse reactions have been reported**, which can not be directly attributed to a possible nocebo effect of the media crisis of September 2017 (symptoms felt most often before this crisis). Moreover, these **adverse effects may involve signs of hypo and hyperthyroidism**, whereas they **mostly occur at normal TSH**.

As the above summary of the report recognizes, **there is no explanation for this phenomenon**, although **it has probably been aggravated by unfavorable circumstances** (monopoly of LEVOTHYROX in France, no pilot experimentation, minimum communication of the ANSM and absent communication from Merck, minimization of symptoms by public bodies, even some doctors, disrespect of associations, media crisis, petitions and court proceedings, etc.).

**Claude Pigement (vice president of the ANSM, with no executive role)**, [interviewed by Le Parisien on January 30, 2018](#), is also concerned with **"the widening gap between the assertions of a medical elite and the word of patients"**, who live daily with their symptoms, and this while the *Kouchner Law* of 2002 and the *Touraine Law* of 2016 have yet reaffirmed the important place of patients.

He considers that **"since there is a total lack of understanding between the public authorities and associations, a precise scientific study of what happened with this medicine becomes necessary**, especially since 67% of patients had normal TSH."

**Need to publish the pharmacovigilance report of 2012 in its entirety; to rethink the communication of the ANSM ... and of the "eminent professors"**

Mr. Pigement estimates that the **publication of the entire pharmacovigilance report of 2012 is necessary** (note: this report, which originated the request to change the formula, is resumed on page 15 and 16 of the report – but has still not been published, despite the requests from the patient associations).

Claude Pigement also outlines a **lack of responsiveness of the ANSM**, which "**underestimated the sensitivity of this drug and did not deliver the appropriate information**", leaving the sick "**devoid and angry**." He finally **denounces the "eminent professors"** who have entrenched behind the "nocebo effect, a simplistic solution".

**Additional information** (mostly in French):

[Point d'actualité sur le Levothyrox et les autres médicaments à base de lévothyroxine : Les nouveaux résultats de l'enquête nationale de pharmacovigilance confirment les premiers résultats publiés le 10 octobre 2017](#), ANSM, 30 janvier 2018 ([rapport complet, 57 pages](#))

McMillan M et al. [Comorbidities, Concomitant Medications, and Diet as Factors Affecting Levothyroxine Therapy: Results of the CONTROL Surveillance Project](#). Drugs R D. 2016; 16(1):53-68.

Hennessey JV et al. [Adverse event reporting in patients treated with levothyroxine: results of the pharmacovigilance task force survey of the american thyroid association, american association of clinical endocrinologists, and the endocrine society](#). Endocr Pract. 2010;16(3):357-70.

[Levothyrox : «Il faut une étude scientifique précise de ce qui s'est passé»](#), Le Parisien, 30 janvier 2018

[Commission Nationale De Pharmacovigilance, compte rendu de la réunion du mardi 27 mars 2012](#)

**On VIDAL.fr**

[EUTHYROX : le Conseil d'Etat rejette une plainte, Merck annonce la fin prochaine de son importation](#) (décembre 2017)

[LEVOTHYROX : premiers résultats de l'enquête de pharmacovigilance de l'ANSM, des zones d'ombre persistent](#) (21 octobre 2017)

[L-THYROXIN HENNING \(lévothyroxine\) : 4 dosages disponibles à partir du 16 octobre](#) (12 octobre 2017)

[Levothyroxine : aides à l'initiation et à la gestion des difficultés, nouvelles importations d'EUTHYROX](#) (5 octobre 2017)

[LEVOTHYROX : précisions et actions suite aux inquiétudes et plaintes de certains utilisateurs](#) (août 2017)

[LEVOTHYROX \(lévothyroxine sodique\) comprimé sécable : nouvelle formule, nouvelles couleurs](#) (mars 2017)

**Cancer de la thyroïde : face au surdiagnostic massif et ses conséquences, le CIRC appelle à la prudence** (août 2016)

Sources : [Le Parisien](#), [ANSM \(Agence Nationale de Sécurité du Médicament\)](#)

# VIVRE SANS THYROÏDE

Forum de discussion - Association loi 1901

[www.forum-thyroide.net](http://www.forum-thyroide.net)



## Analysis of sales & consumption of levothyroxine-based medication in France in 2017

Source Medic'Am 2017

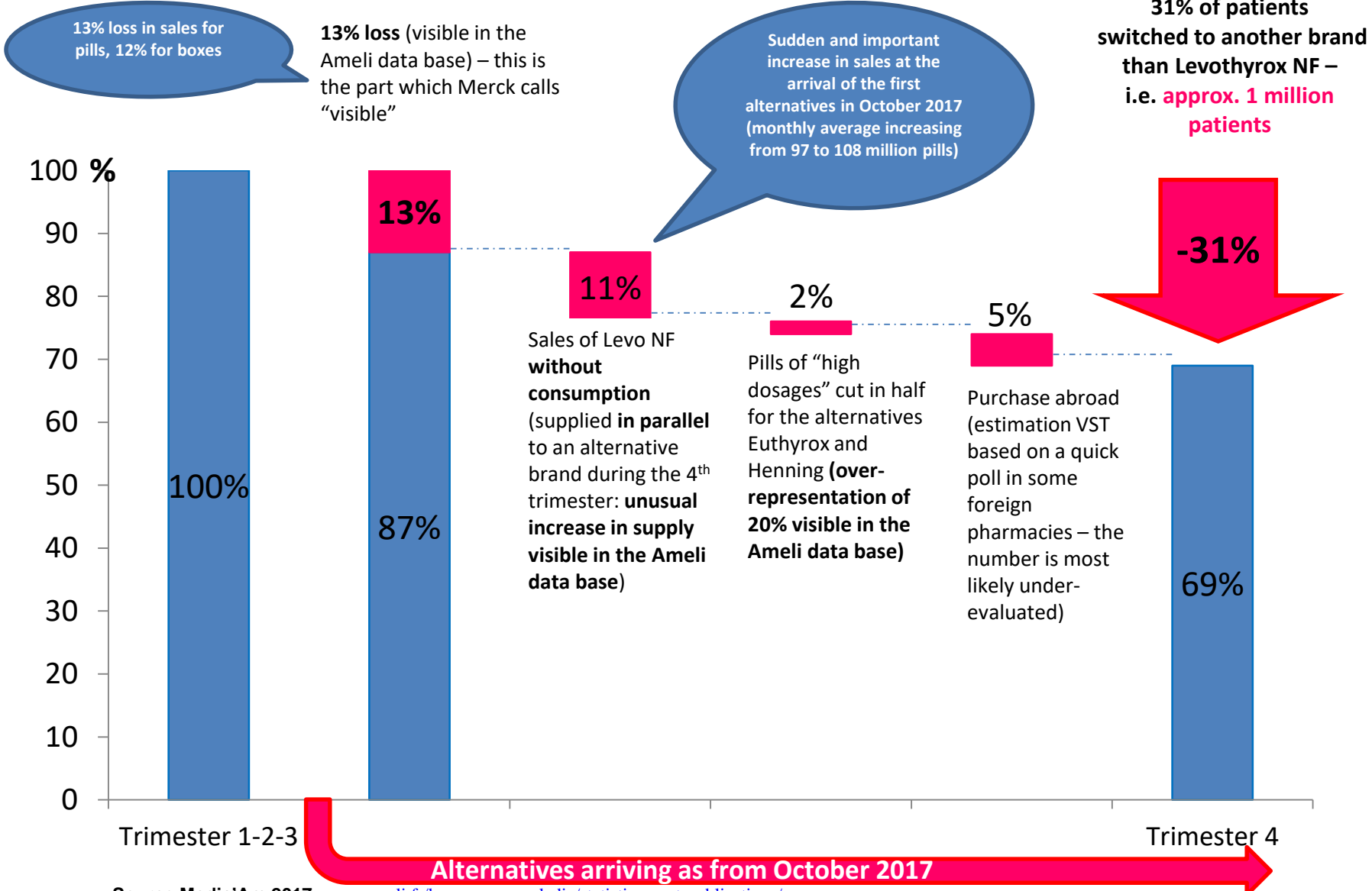
[www.ameli.fr/l-assurance-maladie/statistiques-et-publications/](http://www.ameli.fr/l-assurance-maladie/statistiques-et-publications/)

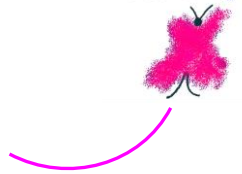
12/03/2018



# Part of consumption of Levothyrox “new formula” in the 4<sup>th</sup> trimester 2017 vs. trimesters 1 to 3 in France

Units : number of pills

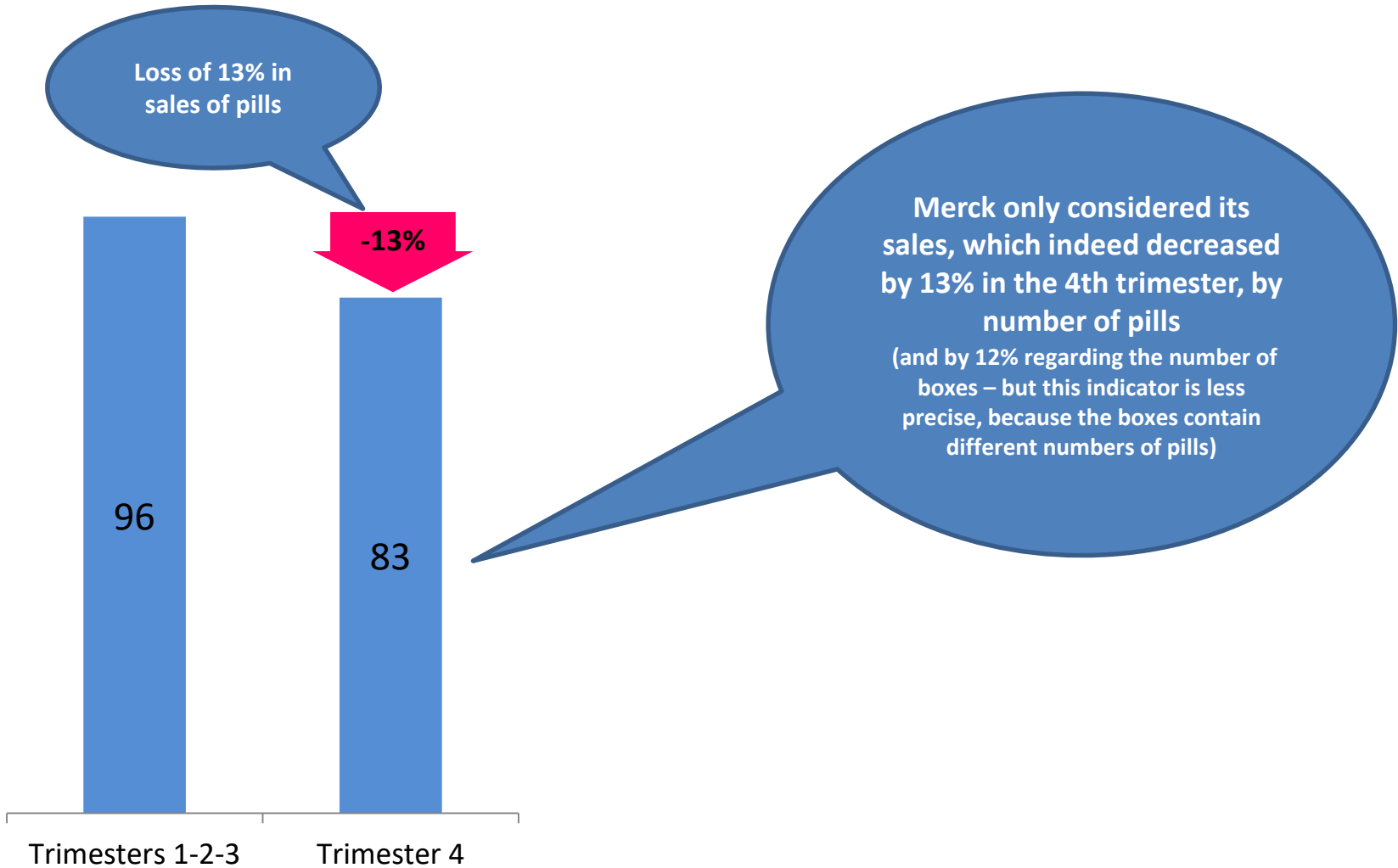




# Sales of Levothyrox in France :

## 4<sup>th</sup> trimester 2017 vs. trimester 1 to 3

Units : millions of pills / month



# Sales of levothyroxine in France (all brands)



## 4<sup>th</sup> trimester 2017 vs. trimester 1 to 3

Units : millions of pills / month

