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HOSPITAL, PATIENTS, HEALTH AND TERRITORIES (HPST) LAW ENFORCEMENT AND PHARMACY EVOLUTION IN FRANCE: TOWARDS A NEW PARADIGM

Ndao Youssou*[1] and Ndiaye Magatte[1]

[1]*Galenic and Legislation, Faculty of Medicine, Pharmacy and Odontology, University Cheikh Anta DIOP of Dakar.

ABSTRACT

In a context characterized by persistent economic constraints and evolving healthcare systems, Law No. 2009-879 of July 21, 2009, known as the "Hospital, Patients, Health and Territories" Act, significantly expanded the public health missions assigned to community pharmacists in France. The objective of this study was to analyze the new paradigm of community pharmacy resulting from this reform. The methodology was based on a literature review including doctoral theses, scientific articles, institutional web resources and legislative texts, with a particular focus on the law. Data were collected from the Dumas, Theses.fr, Google Scholar, PubMed, and Légifrance databases. The results indicate that the law established a model centered on the expansion of pharmacists' clinical and public health roles, particularly in prevention, therapeutic monitoring and care coordination. This evolution is illustrated by the development of vaccination services, organized screening programs especially for colorectal cancer and the use of rapid diagnostic tests. In addition, patient support mechanisms have been strengthened through pharmaceutical consultations, chronic disease management and assistance with transitions of care following hospital discharge. However, the sustainability of this new model depends on reinforced economic support, appropriate regulatory adaptations and continuous health economic evaluation of these expanded professional missions.

KEYWORDS

HPST law, Paradigm, Pharmacist, Enforcement, Mission and Reform.

Author for Correspondence:
Ndao Youssou,
Laboratory of Galenic and Legislation,
Faculty of Medicine, Pharmacy and Odontology.
University Cheikh Anta DIOP of Dakar.

Email: ndao.youssou@gmail.com

INTRODUCTION

Community pharmacies occupy a strategic position within the French healthcare system due to their geographical proximity and accessibility, giving them a central role in providing advice, prevention and primary care. Successive healthcare reforms have reinforced this position in the context of managing chronic diseases. The 2004 reform helped

structure healthcare provision by improving the evaluation and dissemination of knowledge related to procedures, health products and chronic and rare diseases[1]. These latter diseases, which affect nearly 20% of the population, constitute a major public health challenge due to their significant impact on morbidity and mortality[2].

The 2009 law marked a turning point by expanding the community pharmacist's role to include the prevention and monitoring of chronic diseases, while also aiming to improve equitable access to quality care[3]. The increased role of pharmacists as primary healthcare professionals was confirmed during the COVID-19 pandemic, particularly through the prevention and screening measures implemented[4]. This work aims to analyze the new paradigm of community pharmacy in France, examining its foundations, its evolution, and its professional and organizational implications[5].

STUDY OBJECTIVES

General objective

The general objective of our work is to study the new paradigm of pharmacy in France, through the 2009 reform law, marked by the evolution of the role of community pharmacists in France, with new primary care missions.

Specific objectives

More specifically, this study will describe:

The new missions of community pharmacists in public health, particularly prevention and therapeutic support;

The changes expected under the HPST law, particularly regarding fee-for-service remuneration, the development of healthcare networks for patient support and follow-up and the development of pharmaceutical consultations;

The difficulties encountered in the current application of the law.

METHODOLOGY

This is a literature review based on a narrative literature review. The sources used include university theses, scientific articles, documents from the web, as well as legislative and regulatory texts, in particular Law No. 2009-879 of July 21, 2009, known as the "Hospital, Patients, Health and Territories" (HPST) Law, concerning the new missions of community pharmacists.

Data was collected from the following databases and document platforms: DUMAS, THESES.FR, Google Scholar, PubMed, as well as the official Legifrance website (www.legifrance.gouv.fr) for access to legal texts. The analysis focused primarily on identifying and examining the changes introduced by the HPST Law within the pharmacy profession, as well as the expected changes in pharmacy practice within this new regulatory framework.

RESULTS AND DISCUSSION

Recent healthcare reforms have led to a redefinition of the role of the community pharmacist, marked by the assignment of new missions focused on prevention, pharmaceutical support, and care coordination, particularly through the PRADO home-based care program. These changes are accompanied by new regulatory obligations, increased organizational constraints and also renewed practice methods, reflecting a profound transformation of the profession towards a more clinical practice integrated into the patient care pathway.

PREVENTION MISSIONS

Prevention missions constitute a major focus of expanding the scope of practice for community pharmacists. They encompass vaccination, screening, and diagnostic testing, carried out directly in the pharmacy, in a secure and confidential environment, without prior medical consultation.

Pharmacists are now authorized to:

Administer certain vaccines recommended from the age of 11, particularly against seasonal influenza, COVID-19 and tetanus;

Participate in national screening programs, especially the colorectal cancer program, by informing patients and distributing screening kits;

Perform rapid diagnostic tests (RDTs), particularly for tonsillitis and refer patients to a physician when the clinical situation warrants it.

Vaccination in pharmacies

Vaccination in pharmacies can be carried out by community pharmacists, pharmacists working in

mutual or mining relief pharmacies, provided they have completed training that meets regulatory requirements and have filed the corresponding activity declaration.

Furthermore, postgraduate students in pharmaceutical studies are also authorized to administer vaccines, under strict conditions, including:

Regular enrollment in a competent teaching and research unit;

Validation of theoretical and practical coursework related to vaccination;

Practice within the framework of an internship, under the supervision of a clinical supervisor, or within the framework of a substitute certificate[6].

However, students working in pharmacies outside of a university internship framework are not authorized to administer vaccinations.

Vaccination Training

A pharmacist is considered trained in vaccination when they have completed:

Either specific training integrated into their initial training;

Or supplementary training provided by an accredited organization, in accordance with the educational objectives set by ministerial decree[7].

The 10.5-hour vaccination prescribing training meets the requirements defined by the decree of August 8, 2023, and can be taken within or outside of Continuing Professional Development (CPD). These requirements aim to guarantee clinical competence and the safety of procedures performed in pharmacies[8].

Technical and Organizational Conditions of the Pharmacy

The implementation of vaccination in pharmacies requires compliance with precise specifications regarding the layout of the premises, equipment, traceability and risk management. The pharmacy must, in particular, have:

A private space dedicated to pre-vaccination consultations and the vaccination procedure;

Equipment adapted for welcoming patients;

A secure vaccine storage system with cold chain control;

The necessary equipment for injection and emergency care;

Compliant solutions for the disposal of infectious medical waste;

IT tools enabling traceability and data entry into the Shared Medical Record (DMP)[9].

Vaccination also exposes pharmacists to the risk of bloodborne pathogen exposure incidents. As such, pharmacy owners are required to inform and train staff on the procedures to follow in the event of an incident, in accordance with current regulations. The management of infectious medical waste (DASRI) falls under the responsibility of the pharmacist, who must use approved service providers, with potential for pooling resources at the regional or national level.

Vaccines and Populations Eligible for Vaccination in Pharmacies

Community pharmacists are authorized to prescribe and administer vaccines listed in the current vaccination schedule for individuals aged eleven years and older, in accordance with national recommendations. However, this authorization excludes the administration of live attenuated vaccines to immunocompromised individuals.

Pharmacy students with the necessary authorization, under supervision or holding a substitute certificate, may also administer these vaccines. Furthermore, seasonal influenza vaccination may be administered in pharmacies to all individuals aged eleven years and older, regardless of whether they belong to the populations targeted by the recommendations[10].

Community pharmacists are playing an increasingly important role in the prevention, screening and diagnostic guidance of the population. Traceability and monitoring of vaccination procedures, the distribution of colorectal cancer screening kits and the performance of Rapid Diagnostic Tests (RDTs) illustrate this evolution. These activities are governed by a precise regulatory framework designed to guarantee patient safety, the effectiveness of interventions, and continuity of care.

Traceability and Vigilance of Vaccination

Vaccination traceability consists of comprehensively recording each vaccination in the patient's file, including the date, type of vaccine, batch number and route of administration. The use of computerized tools facilitates reliable monitoring and the management of booster vaccinations.

Vaccination vigilance involves the systematic reporting of any suspected adverse event and the continuing education of healthcare professionals to ensure appropriate care. These measures are essential to maintaining public confidence in vaccination programs. Furthermore, the pricing of fees related to vaccination is governed by the national agreement between pharmacists and health insurance[12].

Screening

Colorectal Cancer Screening

Colorectal cancer represents a major public health challenge, with a high incidence and significant mortality in France. Early detection considerably increases the chances of recovery. The distribution of screening kits by pharmacists represents a significant step forward in the screening strategy, in accordance with the decrees of April 1, 2022 and March 31, 2022[13,14].

The pharmacist's role includes

Verifying eligibility.

Referring the patient to a physician if ineligible.

Dispensing the kit and providing information on its use, the limitations of the screening and the procedure to follow in case of a positive result.

Notifying the patient's primary care physician to ensure follow-up.

The kit can be accessed directly from a pharmacy or through a physician, subject to prior verification of eligibility[15].

Rapid Diagnostic Orientation Tests (RDOTs)

Pharmacists can perform certain RDTs for infectious diseases, provided they have suitable premises, appropriate training and have informed the patient's primary care physician. These tests are in vitro diagnostic medical devices performed outside of laboratories and do not replace confirmatory tests.

Patient eligibility criteria

Adults and children ≥10 years.

Spontaneous presentation with symptoms or conditional prescription for antibiotics for group A streptococcal pharyngitis.

Conditional prescriptions are limited to 7 days and specify the dispensing of antibiotics only in the event of a positive rapid diagnostic test (RDT).

The pharmacist selects the RDT based on its performance and strictly follows the manufacturer's instructions and regulatory recommendations[16].

Authorized Rapid Diagnostic Tests (RDTs)

Community pharmacists are authorized to perform four (4) types of Rapid Diagnostic Tests (RDTs):

Capillary blood glucose test: This test is used to detect potential blood glucose abnormalities as part of diabetes prevention campaigns.

Oropharyngeal RDT for group A streptococcal pharyngitis: This test aims to aid in diagnosis when bacterial pharyngitis caused by group A streptococcus is suspected.

Oropharyngeal RDT for influenza: This test helps guide diagnosis when influenza is suspected.

Urine tests to screen for nitrituria and leukocyturia, as part of the evaluation of symptoms suggestive of uncomplicated acute cystitis in women.

These tests are performed to facilitate and expedite the diagnostic process, but they do not replace laboratory analyses and may require further confirmation by other diagnostic methods if necessary.

Rapid Diagnostic Tests for Sore Throat (RDTs)

Authorizing community pharmacists to perform Rapid Diagnostic Tests (RDTs) for sore throats, alongside physicians, aims to contribute to the fight against antibiotic resistance and simplify patient care. Remuneration for this service is determined within the framework of the pharmaceutical agreement.

It is imperative that community pharmacists receive mandatory training to perform RDTs, provided by a training organization independent of companies manufacturing or distributing health products; this training may be part of continuing professional development (CPD) or not. This guarantees the objectivity and quality of the training, as well as the pharmacist's competence in performing RDTs.

To carry out the rapid diagnostic orientation test (RDOT), the pharmacist must follow the following procedure (Figure No.3).

Cases of Cystitis

The diagnosis of a simple, uncomplicated urinary tract infection relies primarily on a patient history to identify typical symptoms, including burning and pain during urination, increased urinary frequency, and urgency, in the absence of risk factors.

In the case of an uncomplicated infection, antibiotic treatment such as fosfomycin is appropriate, in addition to lifestyle and dietary measures.

Three decrees published in the Official Journal on November 30, 2023, now regulate the performance of urine tests by community pharmacists for cystitis screening.

The first decree, dated November 28, 2023, expands the list of urine tests that can be performed by pharmacists, making them eligible for reimbursement by health insurance. The second decree of the same day establishes the list of antibiotics in the appropriate class for treating suspected uncomplicated acute cystitis in women, for which a conditional dispensing prescription may be issued.

Finally, the decree of July 13, 2023, amends that of August 1, 2016, by specifying that urine tests performed by pharmacists as part of an assessment of symptoms suggestive of uncomplicated acute cystitis in women do not constitute a medical biology examination.

Mandatory Training

The principle of the HPST law is to combine, within the Continuing Professional Development (CPD) framework, continuing medical education (CME) and the evaluation of professional practices (EPP).

Members of the medical professions (physicians, dentists, midwives, pharmacists, etc.) and paramedical professions (including nursing assistants and childcare assistants) are required to complete CPD.

The implementation of the Continuing Professional Development (CPD) system, particularly through continuing education for healthcare professionals, is a three-year obligation. Healthcare professionals must therefore fulfill this obligation over a three-year period.

Furthermore, public and private employers are required to enable their employed healthcare professionals to fulfill their CPD obligations.

The law sets the following objectives for CPD

Evaluation of professional practices;

Improvement of knowledge;

Improvement of the quality and safety of care;

Addressing public health priorities;

Medically controlled healthcare spending.

The National Agency for Continuing Professional Development (ANDPC), established by law, certifies the training programs offered after their evaluation by a scientific committee[19].

Pharmaceutical Support

In the pharmacy, dispensing medications and other health products, combined with pharmaceutical analysis and the provision of advice, is the first step in a clinical pharmacy process. It can be supplemented by a pharmaceutical consultation or a medication review[20].

Therapeutic Education

The HPST law incorporated therapeutic patient education (TPE) into the Public Health Code (articles L.1161-1 to L.1161-6 of the CSP) and into the patient care pathway. This is a mission entrusted in particular to community pharmacists (article L.5125-1-1 of the CSP).

To participate in TPE programs, community pharmacists must complete a minimum of 40 hours of training. The pharmacist can thus help the patient understand their treatment, for example by explaining a specific medication administration technique (such as an inhalation system), or by guiding them in learning how to self-monitor a condition like diabetes. Therapeutic patient education (TPE) actions and programs are carried out by a multidisciplinary team, including at least one physician, and depending on the conditions and associated protocols, nurses, occupational therapists, dietitians, or social workers.

Pharmaceutical Consultations

The pharmaceutical agreement specifically provides for three types of pharmaceutical consultations: monitoring of patients taking oral anticoagulants, asthmatic patients taking inhaled corticosteroids and patients taking oral anticancer drugs.

Covered by the French National Health Insurance (Assurance Maladie), these pharmaceutical consultations are for adult patients undergoing treatment with an oral anticoagulant for a foreseeable or actual duration of 6 months or more, or with an inhaled corticosteroid for a foreseeable duration of at least 6 months.

In all cases, the support includes:

An assessment interview (gathering general information about the patient, identifying the area(s) of support to be implemented);

And a thematic interview (follow-up tailored to the support needs, particularly regarding side effects).

One assessment interview and two thematic interviews are conducted during the initial year of enrollment, and at least two thematic interviews are conducted in each of the following years.

Training is required to conduct these interviews. Depending on the type, they require interprofessional coordination between community and hospital pharmacists or with the patient's primary care physician.

In parallel, the new pharmaceutical agreement, published in the Official Journal on April 10, 2022, provides for the implementation of awareness sessions for pregnant women regarding the risks associated with medication use during pregnancy and the importance of vaccination.

Shared Medication Reviews

As required by best practices for dispensing medication in community pharmacies, medication reviews involve identifying and analyzing all of a patient's treatments and working with them to reach a consensus in order to strengthen therapeutic adherence and reduce the risk of adverse drug events. The national pharmaceutical agreement established "shared medication reviews" (SMRs) in 2018.

The eligibility criteria for a shared medication review are:

Age: 65 years and older;

Polypharmacy: at least 5 reimbursed active ingredients prescribed;

Chronicity: a prescription lasting six consecutive months or more (duration observed before or after adherence).

The community pharmacist gathers information and then analyzes all treatments received by the patient. They then transmit their conclusions and recommendations to the treating physician and, if necessary, to other prescribers with the patient's consent. This is followed by consultations to provide tailored advice and assess treatment adherence.

Furthermore, the new agreement provides for an exemption to the eligibility requirements for shared medication reviews for patients residing in nursing homes (EHPADs), which provide accommodation for dependent elderly people who are highly susceptible to iatrogenic risks due to their age and heavy medication use, in order to include them in the target group for the program[21].

PRADO Home Return Service: Principle and Approach

The PRADO service aims to anticipate patients' needs upon their return home after hospitalization. Community pharmacists can participate in this support, designated by the patient themselves. Informed of the patient's discharge by a health insurance advisor, the pharmacist can pay particular attention to the patient's medications to limit the risks of iatrogenic effects. They can also dispense medication at home for isolated patients, without assistance and unable to travel, at the request of the hospital medical team[22].

EXPECTED CHANGES UNDER THE HPST LAW

The HPST (Hospital, Patients, Health, Territories) law marks a profound transformation of pharmacy practice in France, strengthening the clinical, economic and organizational role of the community pharmacist. These changes are based primarily on the recognition of the pharmaceutical act, the evolution of remuneration methods, increased involvement in care pathways, and the development of new public health missions[23].

Recognition and Structuring of the Pharmaceutical Act

The pharmaceutical act of dispensing is legally defined by Article R.4235-48 of the Public Health Code (CSP)[24].

It falls exclusively under the competence of the pharmacist (owner or assistant) or their authorized staff, within the framework of the pharmaceutical monopoly. This act is not limited to the physical delivery of the medication, but is based on a structured professional process including:

A legal analysis of the prescription (authenticity, regulatory compliance, patient identification);

A pharmacotherapeutic analysis (indication, dosage, interactions, compliance with the marketing authorization, consideration of the patient's condition);

An economic analysis, determining reimbursement and generic substitution;

An independent pharmaceutical decision, including the possibility of refusal or exceptional dispensing in the patient's best interest;

Patient support through information, advice and ensuring the proper use of medications.

This approach establishes the pharmacist as a key player in medication safety.

Evolution of the Pharmacy Remuneration Model

Under the HPST law, pharmacy remuneration is gradually shifting from a model based primarily on profit margin to one linked to professional services. Negotiations between pharmaceutical unions (FSPF, USPO, UNPF) and the National Health Insurance Fund resulted in the signing of a memorandum of understanding on January 9, 2014[25].

This memorandum establishes dispensing fees, aiming to partially decouple pharmacists' remuneration from the price and volume of medications. It notably includes:

A fee per box dispensed, introduced gradually (€0.80 in 2015, €1 in 2016);

A specific fee for complex prescriptions;

A concurrent reform of the smoothed, sliding-scale profit margin.

This reform, described as historic by some unions, has nonetheless sparked considerable controversy within the profession due to its varying economic impact depending on the type of pharmacy and numerous operational uncertainties (VAT, billing, the role of supplemental health insurance)[26].

Unit-dose dispensing: a public health lever

Unit-dose dispensing of antibiotics, considered in the context of the fight against antimicrobial resistance, illustrates the expanding role of pharmacists in public health policies. Although planned on an experimental basis starting in 2014, its implementation has been delayed due to the lack of a clear regulatory framework[27,28].

This system would give pharmacists a central role in optimizing antibiotic treatments, while also raising significant organizational, economic, and logistical challenges, particularly regarding remuneration and the management of partially used packages[29].

Integration of pharmacists into healthcare networks

The HPST law promotes the development of multidisciplinary healthcare networks, designed to improve the coordination, continuity, and quality of care, particularly for chronic conditions[30]. Community pharmacists contribute to this network on a voluntary basis through their medication expertise, accessibility and role in therapeutic education and adherence.

Although still underdeveloped, this integration strengthens the recognition of pharmacists as local professionals involved in coordinated care pathways.

Development of pharmaceutical consultations

Paid pharmaceutical consultations are one of the major developments resulting from the HPST law. Initially implemented for patients on oral anticoagulants (AVK), they aim to improve adherence, understanding of treatments and the prevention of iatrogenic complications[31]. These interviews, which are governed by an agreement with the Health Insurance system, are based on a structured, confidential and educational approach[32]. Their rapid increase in use demonstrates their clinical relevance and their acceptability by patients, paving the way for their extension to other chronic conditions, such as asthma.

DIFFICULTIES IN IMPLEMENTING HPST LAW

Since its entry into force, the HPST Law of July 21, 2009, has profoundly altered the organization of the French healthcare system and the practice of pharmacy. It has enabled the emergence of new roles for community pharmacists, while also highlighting structural, economic, and organizational limitations in their effective implementation (Law No. 2009-879 of July 21, 2009).

Persistent Economic Constraints

Despite the introduction of dispensing fees, many pharmacies continue to face economic vulnerability due to the ongoing decline in the prices of reimbursable medications and policies aimed at controlling healthcare spending (National Health Insurance Fund, CNAM)[33]. This situation calls into question the ability of some pharmacies to invest

sustainably in the new roles provided for by the HPST Law, particularly in highly competitive urban areas.

Regulatory Complexity and Administrative Burden

The proliferation of implementing regulations, contractual amendments, and billing procedures associated with the new responsibilities has led to increased regulatory complexity, generating a significant administrative burden for pharmacists (National Pharmaceutical Agreement; Public Health Code).

This administrative burden can hinder the effective adoption of these systems by pharmacy teams[30,31].

Insufficient Training and Support

The success of the new responsibilities stemming from the HPST law requires enhanced skills in pharmacotherapy, communication, and therapeutic education. However, access to continuing education remains unequal depending on the region and the size of the pharmacy, despite the continuing professional development (CPD) obligations stipulated by the Public Health Code (Art. L.4021-1).

Professional Resistance and Lack of Coordination

Resistance persists within the healthcare system, particularly due to differing union positions and the reluctance of some professionals to share patient care. These difficulties limit the effectiveness of coordinated care pathways promoted by the HPST law (HAS)[32].

Variable Acceptability by Patients and Healthcare Partners

Finally, patients' adoption of the new roles remains uneven. The lack of visibility of the pharmacist's expanded role and sometimes insufficient information limit the potential impact of therapeutic support programs (Health Insurance; HAS)[34].

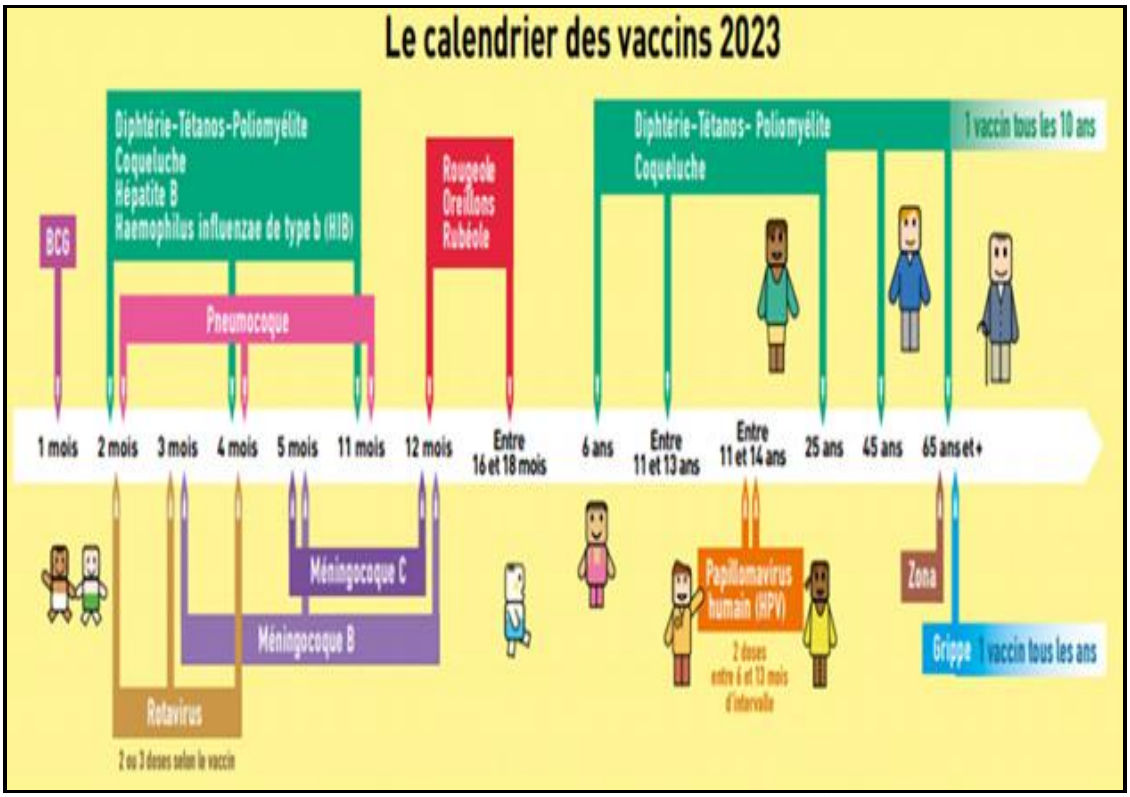

Figure No.1: 2023 Vaccinal Calendar[11]

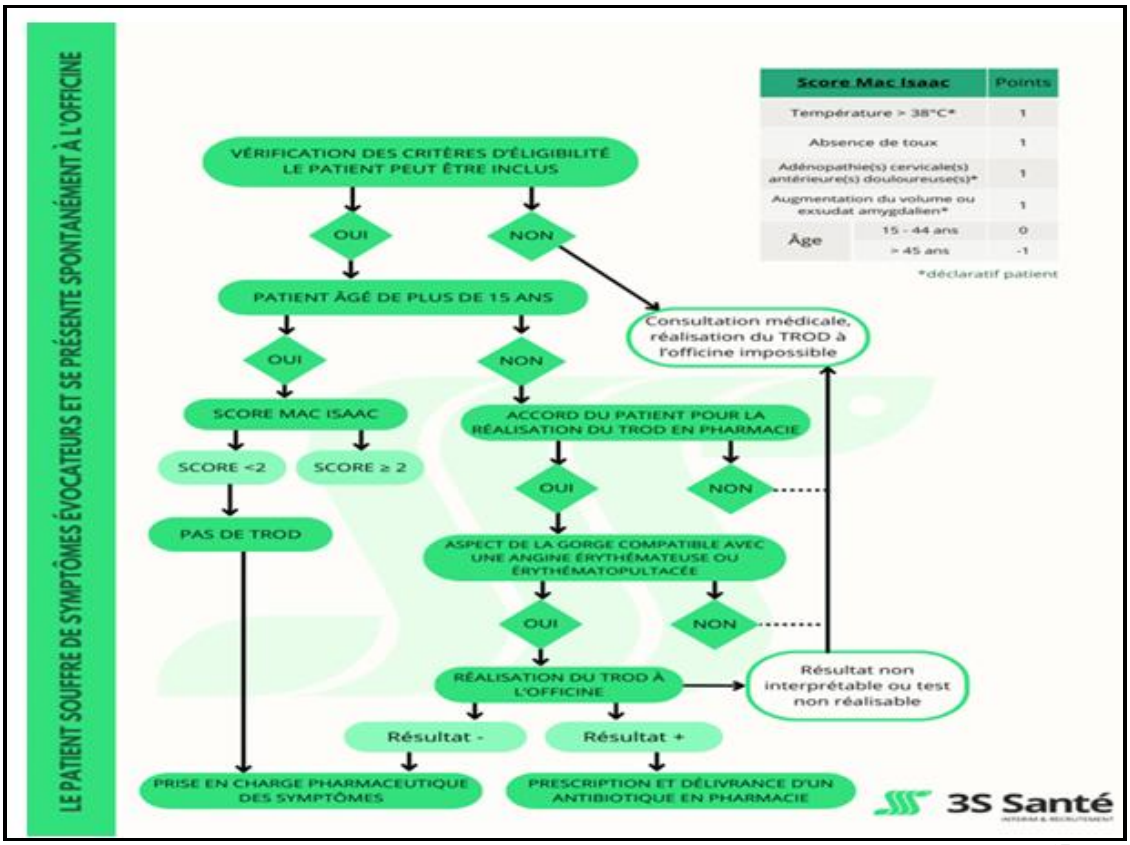

Figure No.2: Decision tree for the management of tonsillitis in pharmacy[17]

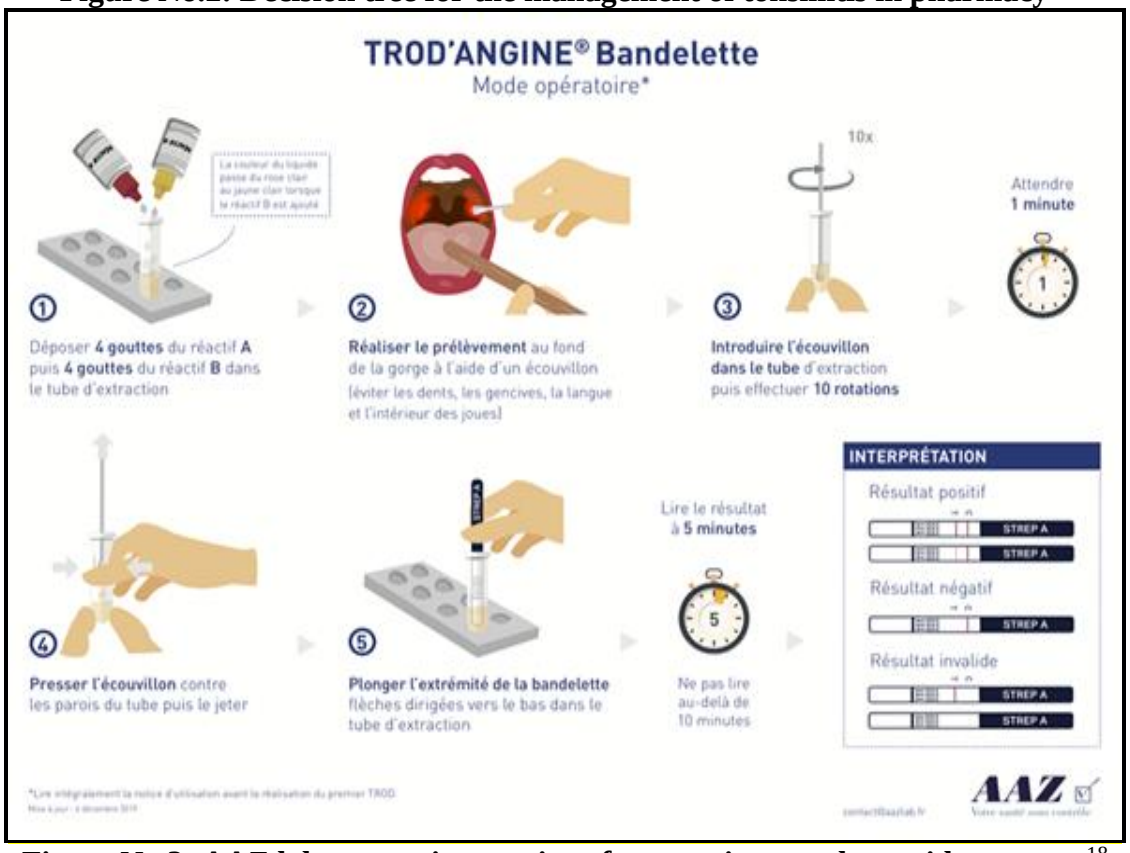

Figure No.3: AAZ laboratory instructions for carrying out the rapid strep test[18]

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CONCLUSION

The 2009 HPST law profoundly redefined role of community pharmacists in France, expanding their responsibilities to include prevention, patient support and participation in care pathways. These changes represent a major lever for recognizing the pharmacist's role in public health and contribute to the efficiency of the healthcare system. At the same time, the transformation of the economic model, particularly through the valuation of professional services via dispensing fees, marks a break with a logic exclusively focused on medication. However, the sustainability of this new paradigm remains conditional on strengthened structural and economic support, as well as an adaptation of legal frameworks, in order to sustainably support the modernization and attractiveness of community pharmacies.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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