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## GIPAMED Study: Validation of a Notification Grid for Pharmaceutical Self-Medication Interventions

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### Abstract

Self-medication can present risks that can result in pharmacists carrying out pharmaceutical interventions (PI). Aim: (i) create a PI notification grid adapted to self-medication (ii) validate it and (iii) analyze the reasons for PIs generated by spontaneous requests from patients in community pharmacies. Method: the study was conducted in 140 community pharmacies in the Auvergne Rhône Alpes region for 3 non-consecutive weeks in 2017 and 2018. Each PI has been notified using a standardized and specifically developed grid. The validity of the internal and external structure of the grid was assessed. Results: 1519 self-medicated PIs were reported. The notification grid was validated with a near perfect match (kappa coefficient 0.94). Overall, the community pharmacists found it to be comprehensive, useful, clear and easy to use. Four ATC classes accounted for nearly 80% of the PIs (respiratory system, nervous system, muscle and skeleton, digestive tract and metabolism). Almost 1/3 of the PIs were generated by requests for prescription-only medicines, followed by optional prescription medicines not indicated for symptomatology and those contraindicated with the pathophysiological status. In most instances, the community pharmacist proposed a therapeutic alternative and/or referred for medical consultation; the proposed solution was accepted in more than 90% of cases. Conclusion: The GIPAMED study facilitated the creation and validation of a specific notification grid for self-medication PIs. It also raises the question of the level of risk avoided through the intervention of the community pharmacist

**Keywords:** Self-medication, Pharmaceutical interventions, Notification grid, Validation, Community pharmacy

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### Introduction

According to the WHO, self-medication is defined by the use of a drug without the need of a health professional<sup>[1]</sup>. Optional prescription medicines (OPMs) are said to be adapted for “responsible self-medication”. Although there is no regulatory definition of a self-medication drug, OPMs and their risk-benefit ratio in particular are suitable for use without previous medical advice; they must be used in the context of an indication for self-care (minor diseases, chronic diseases with an initial medical diagnosis and which do not require medical follow-up); their packaging must be adapted to the dosage and duration of the treatment; the medication leaflet must provide information to the patient so that they can judge the appropriateness of the treatment, easily understand how it is used and know the signs that should encourage them to seek medical advice<sup>[2]</sup>. A number of these medicines, known as “official medication medicines” have been directly accessible to the public in French community pharmacies since 2008<sup>[3]</sup>; they must be displayed in a dedicated space, clearly identified and located in the immediate vicinity of the dispensing stations with access to the pharmaceutical record (PR), so as to allow effective control by the pharmacist<sup>[4]</sup>. The PR, which is a French particularity, identifies, for each health insurance beneficiary who so wishes, all the medicines dispensed over the course of the previous four months, whether prescribed by a doctor or dispensed on the advice or recommendation of the pharmacist. PRs can be found in almost all French community pharmacies<sup>[5]</sup>. In the context of self-medication, the APPSO French guide (pharmaceutical reception of patients without prescriptions), published by the Nation-

al Council of the French Order of Pharmacists, supports the quality of service provided by the dispenser during the reception of the patient or their proxy, the collection of information, as well as making recommendations for the care of the patient in order to optimize pharmaceutical decisions<sup>[6]</sup>. This approach may lead the pharmacist to carry out a pharmaceutical intervention (PI), i.e. “any proposal for modification of drug therapy initiated by the pharmacist or any activity initiated by the pharmacist that benefits the patient”<sup>[7]</sup>. These PIs are performed when the provider identifies a problem that affects the effectiveness or safety of treatment, but they are unfortunately not tracked; they are described as “a discrete activity performed by pharmacists to improve patient care needs”<sup>[8]</sup>. While validated notification grids exist to track PIs on prescription, to our knowledge, there is no validated self-medication PI notification grid<sup>[9]</sup>.

The purpose of this study was to: (i) design a PI notification grid adapted to self-medication (ii) validate it and (iii) analyze the reasons for PIs generated by spontaneous requests from patients in community pharmacies.

Ethics approval

This study was registered with the local correspondent of the French Commission on Information Technology, Data Files and Civil Liberty (n°2016-013), in accordance with French law and reported to the ethics

committee (Comité de Protection des Personnes sud-est 6).

Methodology

Creation of the notification grid for self-medication PIs  
Delphi method

In order to answer all the problems identified during a spontaneous drug request, a standardized grid was created by consensus of multi-disciplinary experts using the Delphi approach. The aim is to obtain an opinion that is as consensual as possible, through a structured communication process that organizes the production, aggregation and modification of the opinions of an independent group of experts. In practice, the Delphi method involves at least three rounds of advice and as many as necessary to achieve maximum consensus within the group; each participant gives his or her opinion, is informed of the opinions expressed by others and is informed of reactions to their own opinion, enabling them to react and arrive at the consensual answer<sup>[10-11]</sup>. The Delphi method also involves analysts, who are responsible for organizing the system, i.e. selecting experts, drafting successive versions of the questionnaires, analyzing and exploiting the results. As part of this study, 11 experts and 2 analysts participated in the creation of the self-medication PI notification grid and three successive rounds, implemented electronically via Lime Survey, resulted in a consensus grid (Table 1).

1. Date of PI
DD/MM/YY : ...../...../.....
2. Information concerning the interlocutor
The interlocutor is : <input type="checkbox"/> patient <input type="checkbox"/> proxy
3. Patient information
Sex : <input type="checkbox"/> Male <input type="checkbox"/> Female
Age : ..... month (< 36 months) or ..... years (≥ 36 months) Children (up to 15 years), specify weight: ..... (kg)
4. Drug requested information
<input type="checkbox"/> Prescription-only medicine (POM)
Name (or common name) : ..... Dosage : ..... Drug form : .....
<input type="checkbox"/> Optional prescription medicine (OPM)
Name (or common name) : ..... Dosage : ..... Drug form : .....
5. Reason for the PI : only one answer possible
<input type="checkbox"/> A Non-compliance with regulations : POM request
<input type="checkbox"/> B Referral for consultation : limit of pharmaceutical advice
<input type="checkbox"/> C Drug not indicated for symptomatology
<input type="checkbox"/> D Drug already used without efficacy, despite optimal duration and adequate dosage
E Drug compliance problem
<input type="checkbox"/> E1 Drug already used but at subtherapeutic dose (proven underdose)
<input type="checkbox"/> E2 Drug already used but at supratherapeutic dose (proven overdose)
<input type="checkbox"/> E3 Drug already used but during a treatment duration abnormally short
F Risk of overdose
<input type="checkbox"/> F1 The patient is already taking the same active substance in self-medication or the request concerns two drugs containing the same active substance
<input type="checkbox"/> F2 The patient is already taking the same active substance on prescription
<input type="checkbox"/> G Drug contraindicated with the pathophysiological status (including allergy)
H Drug Interaction
H1 With an optional prescription medicine (OPM)      Full name (or common name) : .....
<input type="checkbox"/> H1.1 Association contraindicated <input type="checkbox"/> H1.2 Association not recommended
H2 With a prescription-only medicine (POM)      Full name (or common name) : .....
<input type="checkbox"/> H2.1 Association contraindicated <input type="checkbox"/> H2.2 Association not recommended
6. PI detection means (many possible answers)
<input type="checkbox"/> Dialogue with patient or proxy <input type="checkbox"/> Medication history of the patient <input type="checkbox"/> Pharmaceutical record
7. Solution proposed by the community pharmacist (many possible answers)
<input type="checkbox"/> Medical consultation proposal
<input type="checkbox"/> Therapeutic alternative proposal
Full name (or common name): ..... Possible dosage : ..... Pharmaceutical form : .....
<input type="checkbox"/> Adaptation of the drug intake plan: dosage adjustment adaptation (change dose or duration of treatment), administration conditions of the drug)
<input type="checkbox"/> Lifestyle and dietary advice without drug delivery
8. Result of the PI
<input type="checkbox"/> Solution accepted by the patient or proxy
<input type="checkbox"/> Solution not accepted by the patient or proxy : Reason for refusal.....
9. Details of the PI and the proposed solution

Table 1: PI notification grid

**Pre-test of acceptability and feasibility**

The notification grid was tested in 10 community pharmacies to measure its acceptability and feasibility for use. The test pharmacies (5 in Auvergne and 5 in Rhône) were voluntary community pharmacies belonging to the network of local training supervisor associations (AMS Auvergne and AMS Rhône) that did not welcome students on professional training courses. Indeed, those who hosted trainees participated in the validation of the grid.

**Validation of the notification grid for self-medication pls**

**Population and study period**

The validation phase of the grid took place in 140 community pharmacies in the Auvergne- Rhône-Alpes region, during 3 non-consecutive weeks (one in February, one in April and one in May) in 2017 and 2018. Meetings were organized by the study’s pilot committee to train the community pharmacy teams in the study protocol.

**Data collected and study progress**

Each PI produced following a spontaneous drug request was recorded. Some PIs were excluded from the study : PIs on prescription, PIs generated by requests for essential oils, food supplements or medical devices. The PIs were recorded using the grid that collected the following data: patient and drug data, problem identified by the provider, means of detecting the problem, solution proposed by the pharmacist, the acceptance or non-acceptance of this solution by the patient or proxy and the reasons for any refusal (Table 1). The grid also included a free text area to detail the PI.

**Statistical analysis**

The data collected were entered by the providers on a secure university platform on the national RENATER network [12]. The data were then collected using Excel® software (Office 2010, Microsoft Corporation, USA).

**Evaluation of the validity of the grid**

The PIs were reviewed by the pilot committee for validation, checking the completeness of the data entered and their consistency with the PI’s explanatory free text. All analyses were performed with Stata software (version 13, StataCorp, College Station US). A decision matrix was produced, highlighting any recoding of PI patterns between initial and final coding after review by the pilot committee. The data was described by numbers and associated percentages for the categorical variables and by means (and associated standard deviation) for the quantitative variables. Normality was verified by the Shapiro-Wilk test. The internal structure validity explores the coherence of the internal

layout of the specific notification grid. This validity was assessed by studying inter-item correlations and multidimensional analyses to ensure that the items grouped together in the different dimensions studied.

The accuracy (or precision) of the instrument was assessed according to inter-judge reproducibility, the ability to produce comparable results when the measurement is repeated and evaluated by two different pharmacists while the individual’s condition remains stable. The kappa concordance coefficients and intra-class correlation coefficients were calculated.

The validity of the external structure was based on the study of the concordance between community pharmacists and expert opinions used as a decision-making reference framework. The analyses described above have been reproduced in this context.

**Satisfaction survey**

User satisfaction was also assessed using a questionnaire targeting the completeness of the grid items, utility, clarity and ease of use of the grid.

The measurement of grid acceptability was based on the calculation of missing data for each item; it was considered applicable if the conditions of use showed that the cost of implementation is modest, acceptability by subjects and the pharmaceutical community is high, and the time to complete the grid is low.

**Results**

**Validation of the notification grid for self-medication pls**

With regard to the recommendations, a minimum of 50 to 100 subjects is required for the validation step to study inter-judge fidelity and exploratory multidimensional analyses respectively (83). These numbers were successfully achieved as the validation phase took place in 140 community pharmacies, for three non-consecutive weeks and for any PI carried out following a spontaneous request for a drug.

Thus, 1519 PIs were analyzed. 36 PIs were not included in the study (11 concerning essential oils, 15 for food supplements and 10 for medical devices). No grid items revealed any missing data.

**Concordance rate**

The review of the 1519 PIs led to a recoding of some PI reasons, thus generating a decision matrix (Table 2). For example, 490 PIs were initially coded “pattern A”; 480 of them were correctly coded (2 were recoded “pattern B”, 6 “pattern C”), 1 “pattern E” and 1 “pattern G”). Thus, a 95% agreement rate between the initial and final codification was observed. This corresponds to a Kappa coefficient (concordance measure) of 0.94, thus reflecting an almost perfect concordance.

		Final coding								
		A	B	C	D	E	F	G	H	Total
Initial coding	A	480	2	6	0	1	0	1	0	490
	B	14	105	0	0	0	0	0	0	119
	C	1	10	347	0	1	0	1	0	360
	D	0	0	0	31	0	0	0	0	31
	E	1	1	7	0	42	0	0	0	51
	F	0	0	2	0	0	65	2	0	69
	G	1	1	10	0	0	1	295	2	310
	H	0	0	2	0	0	0	9	78	89
Total		497	119	374	31	44	66	308	80	1519

Table 2: Decision Matrix

**Evaluation of the satisfaction of the use of the grid by community pharmacists**

This evaluation showed the following points: The grid was considered “quite exhaustive” by a large majority of community pharmacists (71.10%) while no community pharmacist described it as “not at all exhaustive”. Its usefulness was rated on a scale of 0 to 10 and obtained an average of 7.71 (+/-1.08), with a minimum score of 5 and a maximum score of 10. Its clarity was considered “quite satisfactory” for 83.50% of the community pharmacists. Finally, 90.70% of the community pharmacists found the grid “easy to use”.

**Analysis of notified pls**

**Characteristics of patients affected by PIs**

52.6% of PIs were female (796) and 47.4% male (718). The patient was 18 to 64 years of age in nearly 70% of cases (68.7% of PI, 1043), 65 years of age and over in 17.0% (259) of cases and under 18 years of age in

10.8% (164) of cases (no response = 53). The applicant was the patient themselves in 77.6% of cases (1177) and a proxy in 22.4% of cases (340).

**Drugs requested**

As shown in Figure 1, nearly 80% of PIs (78.7%) involved the following four ATC classes: respiratory system drugs (39.1%, 594) with mainly cough suppressants, decongestants and antihistamines; nervous system drugs (17.6%, 268) with mainly analgesics; muscle and skeleton drugs (11.5%, 174) with mainly non-steroidal anti-inflammatory drugs and digestive tract drugs (10.5%, 160).

**PI reasons**

As shown in Figure 2, more than ¼ of the PIs (77.6%, 1179) were generated by requests for prescription-only medicines (POMs) (32.7%, 497) or requests for OPMs not indicated for symptomatology (24.6%, 374), or requests for OPM drugs contraindicated with the pathophysiological status (20.3%, 308). It should be noted that no PI has been recorded for interaction with other OPMs (H1 reason).

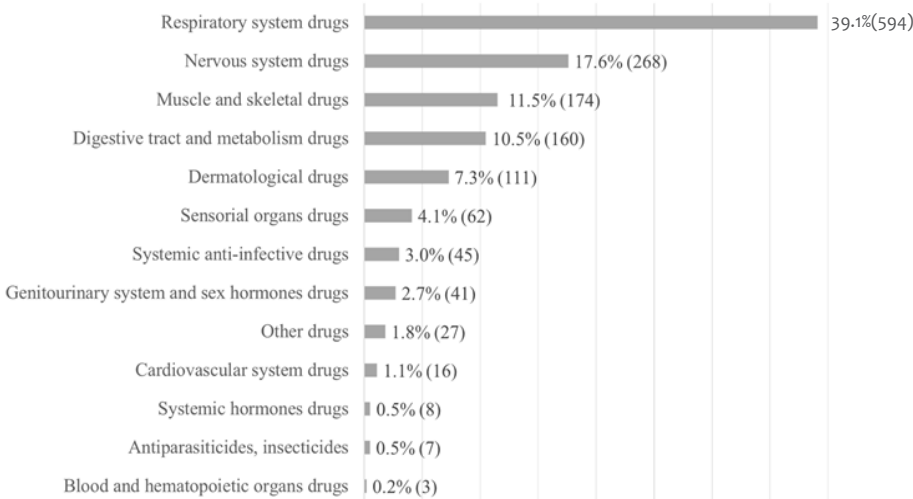


Figure 1: ATC classes of drugs requested

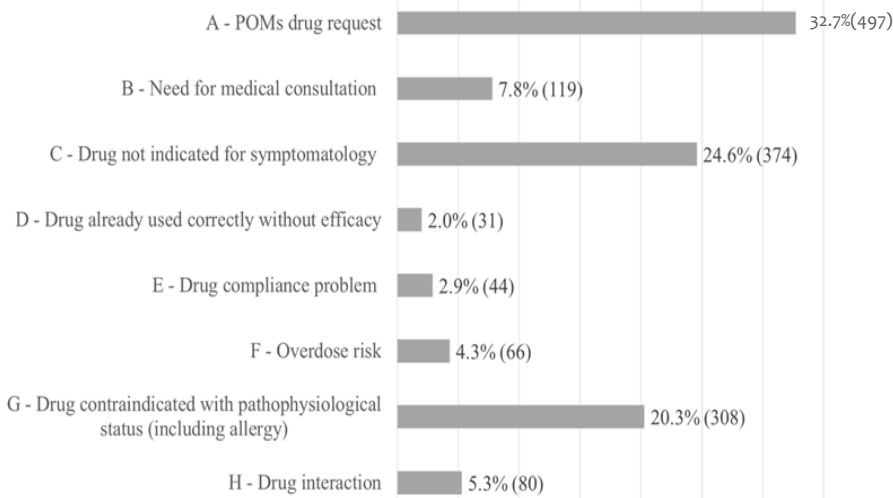


Figure 2: PI reasons



### POM requests

Four main ATC classes were involved. The largest class was respiratory system drugs (32.2%, 160) with mainly opium-derived alkaloid antitussives (codeine, dextromethorphan and pholcodine), corticosteroid decongestants (tixocortol) and sympathomimetics (naphazoline) and antihistamines (desloratadine). Nervous system drugs were the second largest class (17.5%, 87) with mainly opioid analgesics (codeine, tramadol), benzodiazepines (zolpidem). Dermatological drugs (10.3%, 51) with spontaneous requests for topical antibiotics (fusidic acid) or dermocorticoids (betamethasone) and drugs for the digestive tract (9.9%, 49) with mainly omeprazole requests were also present.

### Requests for drugs not indicated for symptomatology

Three quarters of the requests involved respiratory system drugs (47.9%, 179), digestive tract drugs (19.3%, 72) and dermatological drugs (8.3%, 31). In terms of the respiratory system medicinal products, ENT drugs (cetirizine, pseudoephedrine, maleate pheniramine) and pneumological drugs (oxomemazine, pentoxyverine, helcidine) were also present. Digestive tract drug requests recorded were mainly gastroentero-hepatology drugs (bisacodyl, diosmectite, saccharomyces boulardii).

### Requests for drugs contraindicated with the pathophysiological status

Nearly 90% of these were respiratory system drugs (55.5%, 171), nervous system drugs (19.2%, 59) and muscle and skeletal drugs (13.3%, 41). Thus, among the drugs of the respiratory system, the molecules previously mentioned were found. The other drugs were mainly represented by antipyretic analgesics (ibuprofen, paracetamol, acetylsalicylic acid).

### PI detection means

In more than 95% of cases, the PIs were the result of the dialogue alone or in combination with a history/PR check (dialogue alone: 86.4%, 1304; dialogue associated with the consultation of the history and/or the French PR: 9.4%, 143).

### Solution proposed by the community pharmacist and level of acceptance

Nearly 3/4 of the PIs (73.9%, 1122) resulted in the proposal of a therapeutic alternative by the community pharmacist, nearly 1/3 (33.1%, 503) resulted in a medical consultation being offered; in nearly one in ten cases (9.8%, 149), the community pharmacist recommended hygiene and dietary advice and in 6.5% of cases (99) the community pharmacist proposed a dosage adjustment. The solution proposed by the community pharmacist was accepted in 91.6% of cases (1392).

### Discussion

In summary, 1519 self-medicated PIs were recorded using a specific grid. This was validated with a kappa coefficient of 0.94, reflecting an almost perfect agreement. Overall, the evaluation of satisfaction in community pharmacists showed the completeness of the grid, its usefulness, clarity and ease of use. Four ATC classes accounted for nearly 80% of the PIs (respiratory system, nervous system, muscle and skeleton, digestive tract and metabolism). Almost 1/3 of the PIs were generated by requests for POMs, followed by requests for OPMs not indicated for symptomatology and requests for OPM drugs contraindicated with the pathophysiological condition. Most often, the community pharmacist proposed a therapeutic alternative and/or referred the patient for medical consultation; the proposed solution was accepted in more than 90% of cases.

Regarding the limitations of the GIPAMED study, it was conducted over 3 non-consecutive weeks that did not fully take seasonality into account and probably resulted in an overestimation of the PIs generated by a drug request related to issues in the respiratory system.

In addition, the high proportion of PIs related to a drug request to POMs presented a study bias. Indeed, the regulatory status of pain and cough drugs based on codeine and derivatives (ethylmorphine, dextromethorphan, noscapine) were modified in France in July 2017, following two deaths of adolescents linked to diverted use<sup>[13]</sup>; initially OPM, these drugs became prescription-only. In addition, the study was carried out in a single region, Auvergne-Rhône-Alpes, and concerned only 140 community pharmacies out of more than 21,000 in France. Finally, the number of reported PIs was not related to the total number of self-medication dispensations, as this data was not collected in the study. However, previous work on spontaneous requests for ibuprofen or pseudoephedrine (IPADAM study) had estimated that PIs for these target molecules generated 6.7% of the requests<sup>[14]</sup>. In Germany, Eickhoff et al. had estimated self-medicated PIs at 17.6% for all molecules combined<sup>[15]</sup>. Despite these limitations, the notification grid proposed in the GIPAMED study has been validated, proving robust in terms of the validity of its internal and external structure.

Regarding the analysis of PIs reported with this grid, the results are generally in accordance with the scientific literature, although relatively few studies have targeted self-medicated PIs. Some of them included both POMs and OPMs, making it difficult to analyze the data of OPMs alone<sup>[16-18]</sup>. In addition, the notification grids used differ and the molecules available without a prescription may vary from country to country<sup>[16-18]</sup>. However, all studies agree on the drug classes involved, mainly reporting self-medication analgesics, NSAIDs or respiratory system drugs. In the Eickhoff et al. study, which included over 12,000 self-medicated PIs, nearly three quarters of reported PI reasons were inappropriate self-medication, inappropriate product requested, use of the drug for too long (including drug abuse) or inappropriate dosage. A therapeutic alternative was proposed in almost 30% of cases and a referral to a medical consultation in 40% of cases<sup>[15]</sup>. On the other hand, the IPADAM quanti study had attributed almost half of the PIs reported in spontaneous requests for ibuprofen or pseudoephedrine to a contraindication<sup>[14]</sup>. In descending order, other reasons listed were non-indication, overdose, drug interaction, redundancy, underdose and allergy. The solution proposed by the community pharmacist (therapeutic alternative, dosage adjustment, medical consultation) was accepted in 9 out of 10 cases<sup>[14]</sup>.

The analysis of the PI motives of the GIPAMED study highlighted the role of community pharmacists as guarantors of the security of dispensing. Thus, this analysis revealed risks avoided thanks to the community pharmacist's intervention when requesting respiratory system drugs, analgesics including paracetamol, NSAIDs or derivatives and drugs for the digestive tract. Examples of respiratory drugs include PIs generated by pseudoephedrine requests in the context of contraindication (severe or unbalanced high blood pressure, glaucoma, uretro- prostatic disorders, history of stroke or convulsions). Other examples include PIs generated by oxomemazine requests in the context of non-indication (fat cough). Concerning paracetamol, the main analgesic involved, it is worth noting that PIs generated by an overdose (supra- therapeutic dosage or simultaneous use of two drugs containing paracetamol), by a contraindication (effervescent form and high blood pressure) or by a non-indication were included. For NSAIDs and derivatives, ibuprofen was the molecule most often involved. Examples include PIs generated by contraindication (pregnancy from the 6th month, suspicion of dental abscess, renal failure, suspicion of chickenpox) and drug interaction (oral anticoagulants) or overdose (supra-therapeutic dosage or simultaneous use of two drugs containing ibuprofen). For example, for drugs for the digestive tract, we can mention the PIs generated by a non-indication with regard to symptomatology (bisacodyl and risk of laxative disease) and

those generated by a contraindication (diosmectite and infant). This analysis is supported by the scientific literature. Thus, Laccourreille et al. reported the interest of pseudoephedrine as a nasal decongestant but also the dangers and limitations of its use<sup>[19]</sup>. Schmiedl et al. have shown that the consumption of paracetamol, NSAIDs and derivatives can cause serious adverse reactions leading to hospitalization of patients<sup>[20]</sup>. In patients experiencing pain, Mehuys et al. have shown that analgesics (paracetamol and/or NSAIDs), often used in migraine or arthrosic pain, can lead to use in supra-therapeutic or prolonged dosage over several years with a heightened risk of drug abuse, particularly for paracetamol<sup>[21]</sup>. In addition, Shiffman et al. have highlighted the need for increased vigilance when dispensing paracetamol as self-medication, particularly in relation to winter diseases, as exposing the patient to the consumption of the molecule in supra-therapeutic doses in the same drug or in several of them and may increase the risk of hepatotoxicity<sup>[22]</sup>. In addition, the request for ibuprofen for dental pain leading to the suspicion of dental abscess has also been reported, whereas this molecule is formally contraindicated, without initiated antibiotic therapy, exposing the patient to cervico-facial risk<sup>[23-24]</sup>. Similarly, recent work by Noergaart has investigated the long-term use of stimulant laxatives such as bisacodyl, advising against their use beyond four weeks<sup>[25]</sup>. Finally, particular attention is necessary to certain at-risk populations (children, pregnant women and the elderly)<sup>[26-28]</sup>.

## Conclusion

The community pharmacist is a key player in public health, guaranteeing the safety of dispensing. Developing responsible self-medication means supporting the patient with more autonomy, within the limits of pharmaceutical advice, while responding to current issues of societal change and access to primary care. The traceability of PIs in self-medication is a necessary prerequisite to strengthen the pharmaceutical act.

The GIPAMED study facilitated the creation and validation of a specific notification grid for self-medication PIs. The high acceptance rate of PIs notified through this grid has demonstrated the recognition of the role of community pharmacists by patients. The study also raises the question of the level of risk avoided through the intervention of the provider. An avoided risk rating scale should be developed.

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