

PHARMACEUTICAL OPINION

1. WHAT IS A PHARMACEUTICAL OPINION?

A Pharmaceutical Opinion is a reasoned decision,

- drawn up under the authority of a pharmacist;
- concerning the pharmaceutical relevance of a prescription, a test or a request from the patient;
- lodged in the community pharmacy;
- and which must be communicated on a standardised document to the prescribing physician when he is asking for reappraisal, or when he is justifying the refusal or amendment of his prescription officially.

2. WHAT IS THE PURPOSE OF A PHARMACEUTICAL OPINION?

Dispensing at the community pharmacy of products (medicines and medical appliances), whether prescribed or not, aims to ensure on the one hand that the products are compatible with one another (R 5015-48 of the French Public Health Code (CSP)), and on the other hand that they are suitable for the patient (R 5015-60 and R 512-3 – paragraph 1 of the CSP), and finally to give plenty of relevant advice.

Analysis of the request (whether or not there is a prescription), supplemented by questioning the patient, his representative, or perhaps even the doctor, **is a complex process**.

This process can end with:

- issuing;
- issuing, after removal of therapeutic or regulatory doubt;
- issuing in an emergency situation;
- amendment of the treatment;
- refusal to issue
with all possible variants (total or partial refusal, amendment of proprietary medicines, etc.).

Generally up to now, this analysis process **does not in itself leave any trace in the community pharmacy**:

- issuing is formalised either sometimes in accordance with regulations by entry in the prescription register (products listed **I & II**, narcotics and preparations), or in terms of accounting through billing;
- refusal to issue gives rise only to an entry in the prescription register.

However, when the dispensing is complex (regulatory difficulty, therapeutic doubt, etc.), it is necessary to **make the pharmaceutical action intelligible** and provide the following for it:

- **readability**:
(specify considerations made, evaluate actions, notify about special cases, etc.)
- **memory**:
(provide evidence of the action, monitoring of the patient, management of the community pharmacy, etc.)

- **traceability:**
(find the originator of a dispensation or a prescription, find a product, etc.)
- **opposability:**
(justify an action with regard to the patient, the doctor, the courts, etc.)

In application of the duty of personal performance, enhancing the value of the dispensation, an essential action of the pharmacist, enhancing the value of the community pharmacy, a guarantee of the security of care, preparing for the future, in the face of therapeutic and regulatory challenges, such are the functions of the Pharmaceutical Opinion.

3. WHEN IS THERE A PHARMACEUTICAL OPINION?

Any act of dispensing gives rise to a Pharmaceutical Opinion. The simple billing of a product (as far as it constitutes a written trace of the dispensation) is implicitly but necessarily, in the eyes of the law, the result of a conclusive analysis.

On the other hand, the Pharmaceutical Opinion is:

- **formalised** when there exists a complex notification, a doubt whether removed or not, a follow-up requirement, an original intervention, a known vulnerability, pathogenic behaviour, specific precautions for use, a particular substitution, or a need for information internal to the community pharmacy;
- **communicated** when the law so dictates (in the case of refusal or amendment) or if the pharmacist judges it useful to give an account to the prescribing physician of precise information which may be useful to him. *Formal communication is a condition of legal opposability.*

The PO is an *instrument of therapeutic cooperation*, which clarifies the responsibilities and objective and enhances the value of knowledge and communication between doctors and pharmacists.

4. HOW IS THE PHARMACEUTICAL OPINION PRODUCED?

Having to **give an account of the analyses, reasons and decisions of the pharmacist**, the Pharmaceutical Opinion implies:

- A rigorous methodology for collecting information;
- An accurate and legible transcription of this information.

4.1 Structure of the Pharmaceutical Opinion

The standardised document comprises:

- identification of
 - the patient
 - the community pharmacy
 - the originator of the dispensation
 - the prescribing physician (if applicable)
- the nature of the problem
- the arguments of the pharmacist
- any proposal of the pharmacist
- the source of the information justifying the intervention of the pharmacist

- any reminder of medical arguments which motivated the prescription (therapeutic intention)
- decision
- any informing of the patient
- signature (validation)
- date.

4.2 Form of the Pharmaceutical Opinion

The Pharmaceutical Opinion, a standardised document, can be produced equally well either manually or by computer means, if all the instructions are complied with.

But the use of computers will, with great ease and efficiency, allow:

- its development (detection software and databases);
- and its operation through files linked to the patient (pharmacotherapeutic monitoring), or to the product (pharmacovigilance), etc.

The P.O. is therefore an instrument of dispensing, monitoring, and file and information management.

4.3 Communication of the Pharmaceutical Opinion

The Pharmaceutical Opinion formally gives an account of the decision of the pharmacist responsible for the dispensation.

The Pharmaceutical Opinion is **covered by professional secrecy** (Article R 5015-5 of the CSP and Article 226-13 of the (new) Penal Code). Its communication to legal or natural persons, either private or public, not expressly (legally or judicially) authorised, would expose its originator and possibly its recipient, irrespective of his position, to proceedings, in particular legal ones.

It is the responsibility of the pharmacist to ensure the confidentiality of the transmission method.

Only the formal communication of the P.O. makes it legally opposable.

a) Communication of a Pharmaceutical Opinion to the patient

The patient has, at his request, **a permanent right of access** to the personal information concerning him. At the end of the analysis process which led to an Opinion:

1. **In the case of compliant issuing,**
the patient or his representative perceives neither difficulty nor any particular pharmaceutical consideration. Informing them officially of the existence of a Pharmaceutical Opinion is consequently not justified and could give rise to a doubt or reluctance on their part, out of all proportion to the aim sought. Its formal communication is not desirable.
2. **In the case of an altered prescription (refusal/amendment),**
the patient or his representative observes a strictly pharmaceutical intervention. Although informing them officially is justified, this must

however remain limited to the duty to provide assistance (in case of possible danger), or the duty to provide advice. The full communication of a Pharmaceutical Opinion goes beyond the scope of this provision of information.

The pharmacist must be careful that the educational principle of the Pharmaceutical Opinion does not impair the trust the patient has in his doctor.

a) Communication of a Pharmaceutical Opinion to the doctor

The Opinion must be communicated each time the regulations so dictate (Article 60 of the Pharmacists' Code of Ethics) or the pharmacist considers it useful (cf. III.3).

Silent lucidity, contrary to the interest of the patient, could be severely sanctioned.

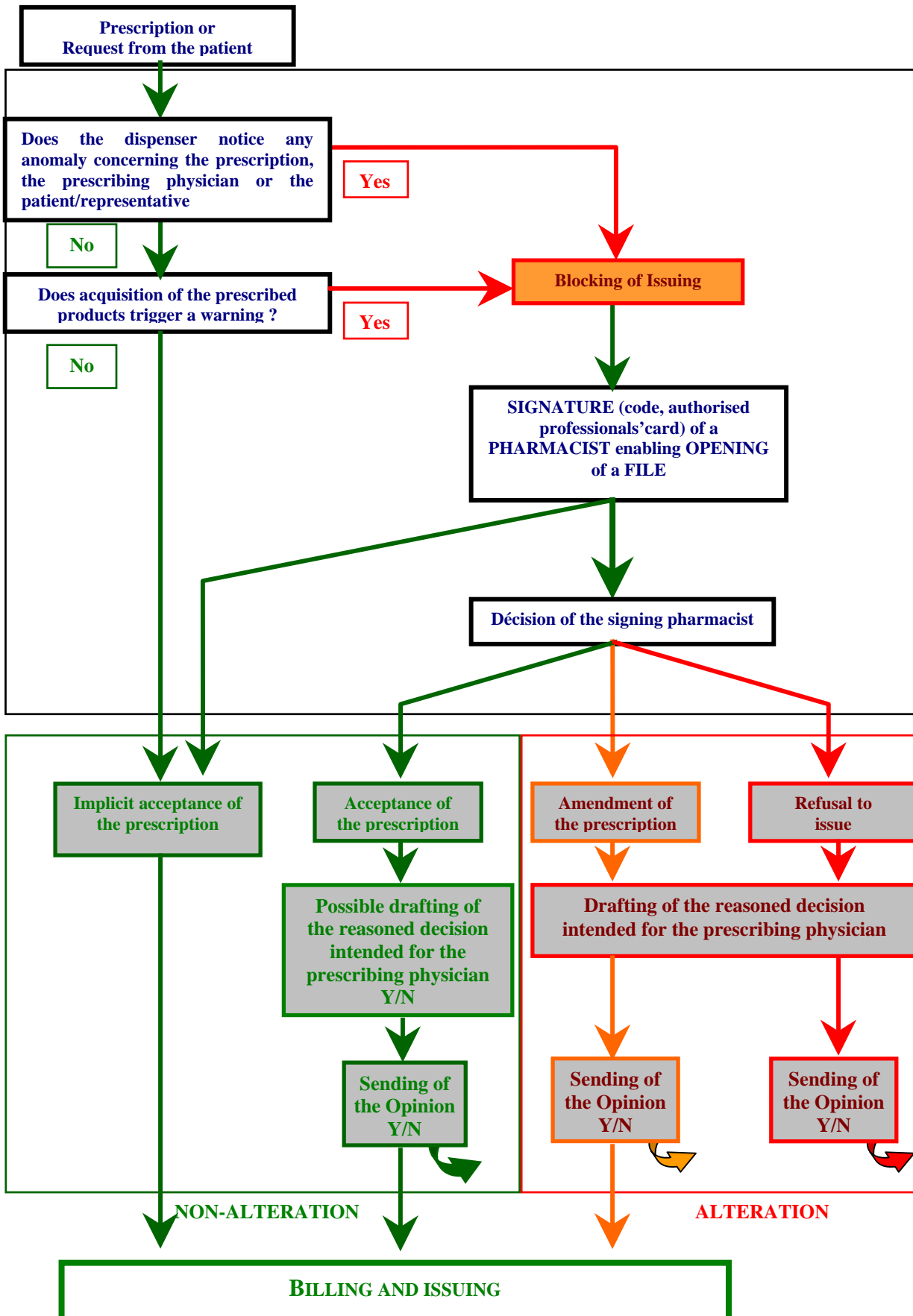
The prescribing physician must be placed in a position to react effectively within satisfactory times.

Formal communication of the PO will therefore come most often in confirmation and/or clarification of a telephone notification, for entry into the medical file.

b) To third parties

Communication of this type of information of a personal nature to third parties not expressly authorised (by the law or the courts) is punishable by legal sanctions.

PHARMACEUTICAL OPINION: DECISION TREE



PHARMACEUTICAL ANALYSIS

Subsequent access for product /patient / doctor file

RECORDING

PHARMACEUTICAL OPINION¹

(Copy intended for the prescribing physician, the duplicate being lodged in the community pharmacy)

Personal document protected by professional secrecy

(Pharmacy's stamp & date)

Doctor:

Specialty:

Dept: Functional unit

ADELI No.:

SUBJECT: (cf. front side photocopy)

Treatment being introduced Renewal **Prescription dated:** / / 2000 drawn up for

PATIENT:

Surname: Forename:

Identification No.: Date of birth: / / or age

(NI or file No.)

M F Weight:kg Height:cm

NATURE OF THE PROBLEM: Medicines concerned (INN, galenical form, dosage and posology)

<input type="checkbox"/> Non-observance	
<input type="checkbox"/> Medicinal interaction(s)	
<input type="checkbox"/> Contra-indication	
<input type="checkbox"/> Posology anomaly	
<input type="checkbox"/> Undesirable effect(s)	
<input type="checkbox"/> Indication not in the marketing authorisation	
<input type="checkbox"/> Other (medication reserved for hospital, special-status medication, etc.)	

PHARMACEUTICAL ARGUMENT(S)

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THERAPEUTIC INTENTION(S) OF THE PRESCRIBING PHYSICIAN

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REFERENCE(S)

Dictionary: Data bank: Other:

Contact with the Pharmacovigilance Centre of: on: / / 20

Publishing of a declaration of an undesirable effect liable to be due to the medicine (Cerfa No.10011'01) on: / / 20

DECISION

<input type="checkbox"/> Posology adaptation	<input type="checkbox"/> Change of therapeutic class	<input type="checkbox"/> Patient or representative informed
<input type="checkbox"/> Planning of the treatment	<input type="checkbox"/> Change of INN	<input type="checkbox"/> P.O. communicated
<input type="checkbox"/> Stopping of the medicine	<input type="checkbox"/> Continuation of the treatment	to D

Validated by Position on / / 20 Signature

1 - The Pharmaceutical Opinion is a reasoned decision, drawn up under the authority of a pharmacist, concerning the pharmaceutical relevance of a prescription, a test or a request from the patient, lodged in the community pharmacy, and which must be communicated on a standardised document to the prescribing physician when he is asking for reappraisal, or when he is justifying the refusal or amendment of his prescription officially (cf. Articles R-5015-48 – R5015-60 of the CSP).

EXAMPLE OF USE OF A PHARMACEUTICAL OPINION – CASE 1

Prescribing on a non-secure prescription, produced by word processing, for SKENAN® 100 mg for a 52-year old patient suffering from severe pain of cancerous origin.

The use of secure prescriptions is intended only to ensure the authenticity and integrity of the source.

This prescription for a narcotic medication does not comply with the text of Act 99-249 amending Article R 5194 of the Public Health Code. However, Articles R 5015-48 and R 5015-7 justify the pharmacist in issuing these medicines in an emergency and in the interests of his patient by requesting the prescribing physician to kindly regularise his prescription.

It is therefore appropriate, for reasons of legal obligations and professional interest, to contact the prescribing physician and then send a pharmaceutical opinion in order to keep in memory the reaction of the pharmacist and justify it towards any authority.

EXAMPLE OF FORM COMPLETION No. 1

NATURE OF THE PROBLEM:

Medicines concerned (INN, galenical form, dosage and posology)

<input type="checkbox"/> Non-observance	
<input type="checkbox"/> Medicinal interaction(s)	
<input type="checkbox"/> Contra-indication	
<input type="checkbox"/> Posology anomaly	
<input type="checkbox"/> Undesirable effect(s)	
<input type="checkbox"/> Indication not in the marketing authorisation	
<input checked="" type="checkbox"/> Other (medication reserved for hospital, special-status medication, etc.)	SKENAN® 60 mg 1 tablet 2 times a day x 10 days

PHARMACEUTICAL ARGUMENT(S)

In accordance with our telephone conversation today, despite the failure of formal conformity of the prescription, in view of the urgency and in the interest of the patient, **I confirm my dispensing of the prescribed products**, and request that, in order to regularise it, you kindly **send me a secure prescription bearing the date of our issuing of the medicine**.

THERAPEUTIC INTENTION(S) OF THE PRESCRIBING PHYSICIAN

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REFERENCE(S)

<input type="checkbox"/> Dictionary:	<input type="checkbox"/> Data bank:	<input checked="" type="checkbox"/> Other: CSP – Act 99-249 amending Art. R5194
<input type="checkbox"/> Contact with the Pharmacovigilance Centre of: on: / / 20		
<input type="checkbox"/> Publishing of a declaration of an undesirable effect liable to be due to the medicine (Cerfa No.10011'01) on: / / 20		

DECISION

<input type="checkbox"/> Stopping of the medicine	<input checked="" type="checkbox"/> Continuation of the treatment	<input type="checkbox"/> Patient or representative informed
<input type="checkbox"/> Change of therapeutic class	<input type="checkbox"/> Planning of the treatment	<input checked="" type="checkbox"/> P.O. communicated
<input type="checkbox"/> Posology adaptation	<input type="checkbox"/> Change of INN	to Dr Dupond

Validated by Position on / / 20 Signature

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EXAMPLE OF USE OF A PHARMACEUTICAL OPINION – CASE 2

Prescribing by a gynaecologist/obstetrician of NOLVADEX[®] 20 mg at a posology of 1 tablet for 5 days, from the 4th day of menstruation, for a 33-year old young woman.

The indication described in the PCS¹ reserves Tamoxifen for the treatment of mammary carcinoma.

The contra-indication concerns pregnant women or those breast-feeding².

The indicated posology is unusual and brings to mind the treatment for anovulatory sterility, confirmed by the patient. The prescribing physician contacted confirms the use of NOLVADEX[®] after failure of CLOMID^{®3}.

The prescribing of a proprietary medicine whose therapeutic indication is not described in the marketing authorisation deprives the dispenser of the cover provided by the A.F.S.Sa.P.S.⁴ Furthermore, the absence of any therapeutic indication appearing in the marketing authorisation excludes this proprietary medicine from the list provided for in Articles L.162-4 and L.102-17,15 of the Social Security Code qualifying its acceptance by health insurance. The financial effect can cause worry and frustrate adherence to the treatment of this patient.

However, there may be contra-indications which can be assessed with respect to a given situation and profile. The role of the pharmacist is not to confine himself to an instantaneous and secure acceptance of the prescription possibly leading to his censure, from the sole viewpoint of **regulatory texts** and disregard for **the importance of the health of the patient**.

The pharmaceutical opinion, by formalising the question and its reply, contributes towards clarifying a medicinal therapy and rationalising the dispensation.

EXAMPLE OF FORM COMPLETION No. 2

NATURE OF THE PROBLEM:

Medicines concerned (INN, galenical form, dosage and posology)

<input type="checkbox"/> Undesirable effect(s)	
<input checked="" type="checkbox"/> Indication not in the marketing authorisation	NOLVADEX [®] 20 mg 1 tablet x 5 days outside menstruation
<input type="checkbox"/> Other (medication reserved for hospital, special-status medication, etc.)	

PHARMACEUTICAL ARGUMENT(S)

NOLVADEX[®] is contra-indicated in the case of pregnancy because of some mutagenesis and teratogenesis abnormalities reported in animals. The long half-life of the product (up to 15 days for an active metabolite), implying the presence of the molecule in the organism for 2 to 3 months after stoppage, should be kept in mind. Although having a mechanism of action similar to that of CLOMID[®] (Triphenylethylenic class, cf. 1989 Australian studies enclosed), the ovulation induction indication is not recognised in the marketing authorisation, which excludes this proprietary medicine from reimbursement by CPAMs [health insurances] in this indication.

THERAPEUTIC INTENTION(S) OF THE PRESCRIBING PHYSICIAN

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REFERENCE(S)

<input type="checkbox"/> Dictionary:	<input type="checkbox"/> Data bank:	<input checked="" type="checkbox"/> Other: Art. L 162-4 and L 102-17,15 of the SS Code, ZENZCA product info.
<input type="checkbox"/> Contact with the Pharmacovigilance Centre of: on: / / 20		
<input type="checkbox"/> Publishing of a declaration of an undesirable effect liable to be due to the medicine (Cerfa No.10011'01) on: / / 20		

DECISION

<input type="checkbox"/> Stopping of the medicine	<input checked="" type="checkbox"/> Continuation of the treatment	<input type="checkbox"/> Patient or representative informed
<input type="checkbox"/> Change of therapeutic class	<input type="checkbox"/> Planning of the treatment	<input checked="" type="checkbox"/> P.O. communicated
<input type="checkbox"/> Posology adaptation	<input type="checkbox"/> Change of INN	to Dr Dupond

¹ PCS: Product characteristic summary published in the VIDAL[®] [Health product reference guide].

² Cf. VIDAL[®] 2000, page 1161.

³ NOLVADEX[®] can cause a temporary rise in FSH and LH causing development of the follicle and ovulation. Generally in these women, the hypothalamus appears particularly sensitive to oestrogens and LH-RH secretion is very low.

NOLVADEX[®], through its anti-oestrogenic action at the hypothalamo-hypophyseal system, causes blocking of the negative feedback created by the oestrogens and contributes towards an increase in LH-RH.

⁴ Agence Française de Sécurité Sanitaire des Produits de Santé [French Agency for Health Product Safety].

EXAMPLE OF USE OF A PHARMACEUTICAL OPINION – CASE 3

Prescribing of ZITHROMAX®.

A patient went to see his doctor for a bronchial infection.

When he arrived at the community pharmacy, the pharmacist knew this patient was on DHE for his migraines, which was confirmed by the therapeutic history (computerised tool).

EXAMPLE OF FORM COMPLETION No. 3

NATURE OF THE PROBLEM:

Medicines concerned (INN, galenical form, dosage and posology)

<input type="checkbox"/> Non-observance	
<input checked="" type="checkbox"/> Medicinal interaction(s)	ZITHROMAX® and Dihydroergotamine Sandoz®
<input type="checkbox"/> Contra-indication	
<input type="checkbox"/> Posology anomaly	
<input type="checkbox"/> Undesirable effect(s)	
<input type="checkbox"/> Indication not in the marketing authorisation	
<input type="checkbox"/> Other (medication reserved for hospital, special-status medication, etc.)	

PHARMACEUTICAL ARGUMENT(S)

Concomitant taking of Dihydroergotamine Sandoz prescribed earlier. Contra-indication between azithromycin and DHE by inhibition of the hepatic metabolism of DHE by the macrolide, entailing a risk of ergotism with possibility of necrosis of the extremities.

Proposal (telephoned): Exchanging of ZITHROMAX® for ROVAMYCINE®, a macrolide having the action spectrum without the interaction risks.

THERAPEUTIC INTENTION(S) OF THE PRESCRIBING PHYSICIAN

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REFERENCE(S)

<input type="checkbox"/> Dictionary:	<input checked="" type="checkbox"/> Data bank: Officialis	<input type="checkbox"/> Other:
<input type="checkbox"/> Contact with the Pharmacovigilance Centre of: on: / / 20		
<input type="checkbox"/> Publishing of a declaration of an undesirable effect liable to be due to the medicine (Cerfa No.10011'01) on: / / 20		

DECISION

<input type="checkbox"/> Stopping of the medicine	<input type="checkbox"/> Continuation of the treatment	<input type="checkbox"/> Patient or representative informed
<input type="checkbox"/> Change of therapeutic class	<input type="checkbox"/> Planning of the treatment	<input type="checkbox"/> P.O. communicated
<input type="checkbox"/> Posology adaptation	<input checked="" type="checkbox"/> Change of INN	to Dr
In the same therapeutic class		

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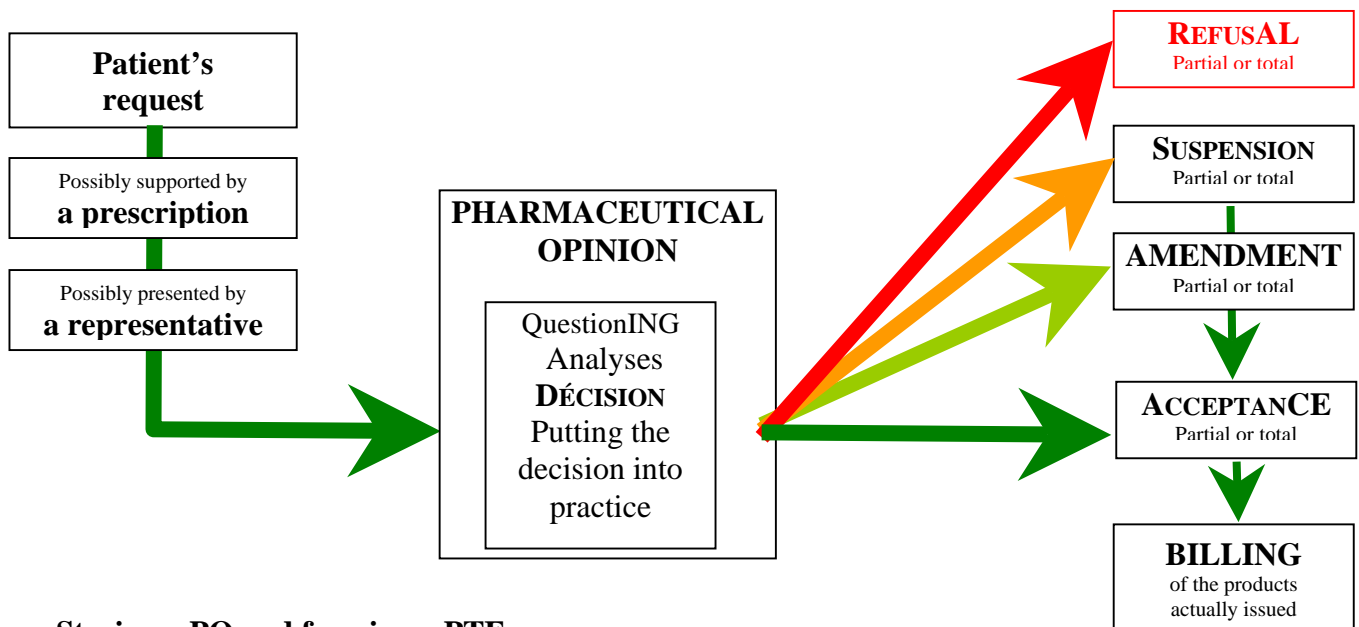
5. FROM THE PHARMACEUTICAL OPINION TO THE PHARMACOTHERAPEUTIC FILE

The dispensing of a medicine, prescribed or recommended, is currently not recorded other than by means of its billing, by accounting software.

This trace is not sufficient for preserving the pharmaceutical analysis made by the pharmacist nor, if need be, justifying and communicating the decision taken (acceptance, suspension, amendment or refusal to issue).

The PO is expressed on a standardised document, using organised data, on a structured presentation.

Prior to any issuing, the Pharmaceutical Opinion process specifies and organises the elements of the pharmacist's considerations, and conditions the material delivery of the medicine (or product), before it is billed.



Storing a PO and forming a PTF

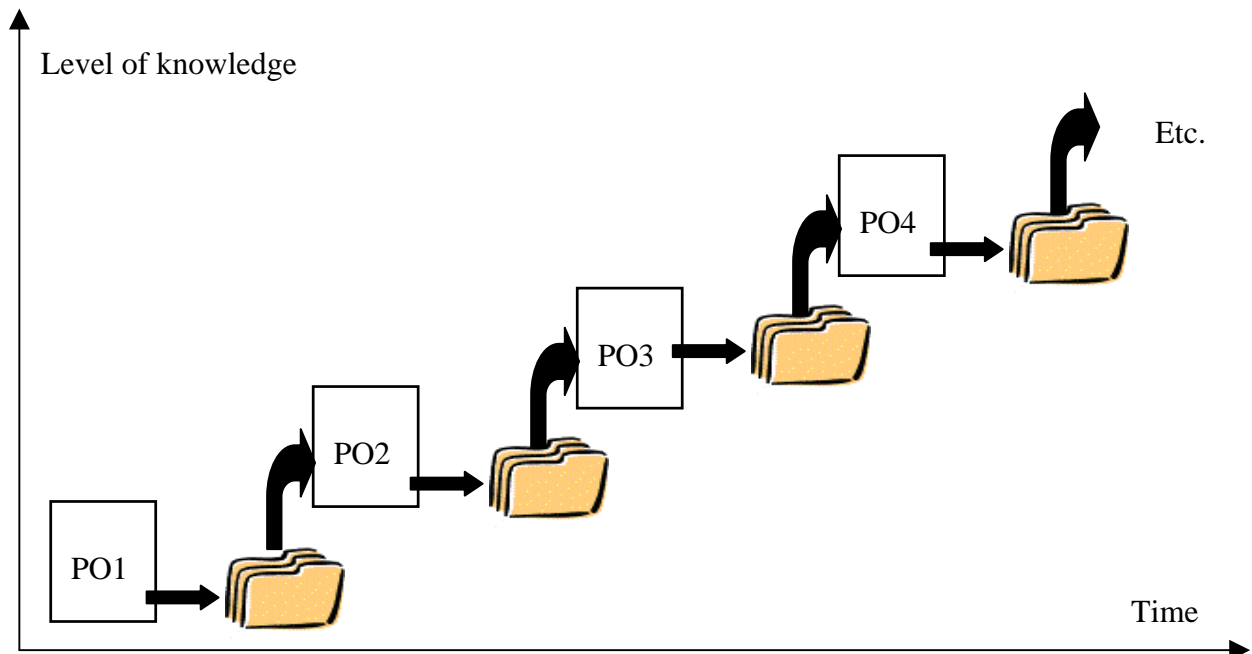
Each PO is retained in order to provide evidence of the action accomplished. The collection of data which constitute the POs, related to a given patient, can be organised to form, for his benefit, a "Pharmacotherapeutic File (PTF)"

Definition:

The pharmacotherapeutic file is the collection of data resulting from the pharmaceutical opinions, related to a patient and with his agreement, and which constitutes all the information of pharmaceutical, medical (information communicated by the doctor connected with a dispensation or a profile), laboratory (relevant analysis results) and administrative (identification) origin, useful for dispensing.

With each PO produced, the PTF is supplied with data as information is acquired by the pharmacist, according to the quality of the relationship established, both with the patient and with the doctor or doctors and other health professionals who may be involved⁵.

Correlatively, the data in the PTF provide successive POs with an importance, both quantitative (amount of information collected) and qualitative (accuracy of the information).



This process mechanically allows the pharmacist to have available a level of information which is continually increasing as a function of time, for honing his analyses and decisions.

The PO constitutes the communication vector of the PTF⁶: it transmits the pharmacist's decision reasoned from patient information as perceived by the dispenser at the time of issuing.

The transmitted PO contains the updated data from the file, possibly also including those acquired at the time of issuing.

Each PO is able to be communicated in order to allow the sharing of information within the context of the Act of 4 March 2002 relating to the rights of patients and the quality of the health system, with the possibility of extraction and use of relevant information, according to many criteria, but subject to legal, ethical and contractual conditions.

⁵ As part of a thematic network, for example.

⁶ PO and PTF are inseparable, since the PTF is the collection of the actions accounted for on the PO. With no pharmaceutical action, the file is devoid of substance and foundation.