Project for the incorporation of *pharmaceutical opinion* and the pharmacotherapeutic follow-up dossier in existing software in community pharmacies

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Since 1996, the quality assurance committee of Central Council A of the Order of Pharmacists has designed a variety of tools aimed a gradually adapting community pharmacy practices to the new context and new challenges.

Today, these tools are leading to concrete measures, with, in addition to the "*Guide d'assurance qualité officinale"* (Community pharmacy quality assurance guide) developed under the aegis of A.-M. Ardouin, *the incorporation of pharmaceutical opinion and the pharmacotherapeutic follow-up dossier in existing software in community pharmacies.*

Led by H. Lepage, the quality assurance committee has, in fact, developed a set of specifications issued to IT service-providing companies. These specifications will be the subject of a complete commented publication in this Bulletin, in order to guarantee their widest possible dissemination, understanding and implementation.

Pharmaceutical Opinion (PO) is a community trademark filed in the name of the National Council of the Order of Pharmacists, not with the purpose of reserving the market but, on the contrary, of guaranteeing its opening up; that is the subject of the present publication.

But it already seems appropriate to provide all pharmacists and interested parties with a synthetic overview of the structure of the reflection and the process, by means of the **table of contents of the specifications** published here.

Purpose of the system

At the current time, the only trace left following the dispensing of a healthcare product that has been prescribed or advised is an accounting one (the invoice) in accounting software acting as a register of prescriptions for the products listed.

However, these software programmes are unable to explain, memorise and, if necessary, communicate, the pharmaceutical analysis made and the resulting decision (issuing of the product, suspension of issuing, agreed treatment modification, refusal to issue the product).

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In order to remedy this shortcoming, the Committee proposes to combine a dispensing aid function with the traditional invoicing function, based on two related concepts: pharmaceutical opinion (A) and pharmacotherapeutic follow-up (B).

A. Pharmaceutical opinion

Foundations

What makes a fundamental distinction between dispensing of a drug and distribution of one is the existence of an analysis, decision-making, advisory and, if necessary, preparatory process. This process and the original responsibility linked to it form the basis for the scientific training, legal monopoly and personal practice of pharmacists.

Yet this essentially intellectual act does not leave any trace in the community pharmacy, despite the complexity of certain hypotheses (regulatory incident, therapeutic doubt, etc.) or the major value of utilisation of the information for therapeutic purposes (pharmacovigilance, prevention of iatrogenic diseases, compliance, adjustment of a treatment, etc.).

"Pharmaceutical opinion" is thus intended to make the act legible, traceable and communicable, according to the process presented in the table of contents.

Definition of a pharmaceutical opinion

A pharmaceutical opinion is a *"justified opinion, established under the authority of a pharmacist, concerning the pharmaceutical relevance of a prescription, a test or patient request, recorded in the community pharmacy and which it is mandatory to communicate on a standardised document to the prescribing physician when it requires revision or when immediate refusal or modification of the prescription is warranted"*.

Any dispensing is the necessary fruit of reflection, which we have termed pharmaceutical opinion. The latter may be implicit, in which case it is certified by straightforward invoicing; but it may also be:

- *formalised* in the event of a complex situation, in which doubts may or may not be raised, a dosage problem, precautions for use, dangerous interactions, contraindications or a specific substitution; of an original procedure, a specific follow-up requirement, known vulnerability, pathogenic behaviour (non-compliance, addictive behaviour, etc.), need for internal information in the community pharmacy, etc.

- *communicated* to the prescribing physician where the Public Health Code demands this (in the event of refusal to dispense the product or modification of the prescription), or if the pharmacist deems it useful to report specific information of therapeutic value, in the patient's interests and with the latter's agreement.

B. Pharmacotherapeutic follow-up

Foundations

In the absence of any pharmaceutical memory, dispensing is generally reduced to its single, safety sense. In fact, the pharmacist cannot follow-up patients, in whom a chronic and/or complex situation would nonetheless call for in-depth pharmaceutical reflection.
And yet the systematic collection of information obtained as each product is dispensed, by straightforward questioning of the patient in the course of the pharmaceutical opinion process, improves safety and quality of care in a number of cases, and also makes it possible to investigate their effectiveness, easily and economically.

In this way, the pharmacist can have at his disposal, in his capacity as a healthcare professional and within the legal framework of this capacity, knowledge of the patient at the time of drug dispensing.

Definition of pharmacotherapeutic monitoring

"*The pharmacotherapeutic follow-up dossier is made up of a collection of pharmaceutical opinions related to a patient with his agreement, forming a set of information from administrative, pharmaceutical, medical (information communicated by the physician related to dispensing or a particular condition) and laboratory (result relevant for analysis) sources, useful for the purposes of dispensing.*"

The data collected during the pharmaceutical opinion process can be ranked in order of themed priority, for example, on the basis of risk factors specific to the disease diagnosed and retained, to elderly patients and/or polymedicated patients, complex protocols, home care, etc.

This set of data is structured into instantly accessible tables related to the patients and establishing the patient profile. Once it has been established in this way, the dossier is then added to each time a product is dispensed, via any questions raised with the patient and the physician, concerning both the content and the context of the request for medications.

Established with the patient's agreement, the pharmacotherapeutic follow-up dossier enables the pharmacist to optimise treatment strategies on the basis of criteria related to safety (much more careful prevention of iatrogenic disease caused by drugs), quality and effectiveness (instigation and evaluation of treatments), ease of use (choice of pharmaceutical form, method of administration) and care economics (optimisation of the resource used), and also to provide the patient with personalised support in his efforts to comply with treatment.

Application to monitoring of type-II diabetes

Initially, pharmacotherapeutic follow-up has been established for patients with type-II diabetes.

Indeed, type-II diabetes shows all the health interest and risk features making it possible to increase patient responsibility and make him an ally in his management. It enables the pharmacist to develop a proactive role in liaison with other healthcare professionals, aimed at developing the quality and safety of out-patient medical care.

In the context of a scientific update, it will be up to computer service companies to work with expert groups recognised by the scientific community to develop these kinds of applications subsequently (asthma, cardiovascular diseases, etc.).

This concept also encourages data-sharing between non-hospital and hospital healthcare professionals and the optimisation of their use for therapeutic purposes. It is founded on the principle of long-term consideration of the individuality of each patient.

Consequently, the human dramas and financial costs related to the misuse of drugs and methods of management of chronic patients, in particular, could be prevented and/or alleviated by the development of an active role for the community pharmacist.

This change in pharmaceutical practices is the subject of debate relative to adjustment of teaching in university training for students and will lead to the organisation of tailored continuing training at a regional level, in liaison with universities.

By objectivizing the pharmaceutical act, the system would thus lead to the systematic implementation of procedures in the community, supplementing the existing healthcare system in the best possible conditions by offering an operational substitute for a hospital provision that is not always either possible or desirable, in the face of major demographic, health and financial challenges.

Specific points relative to the incorporation of the system in existing software programmes

In order to comply with the Committee's requirements, the computerized *Pharmaceutical Opinion* process and the pharmacotherapeutic follow-up dossier must meet the recommendations described in the specifications already communicated to service companies.

Both these and databanks retain full freedom in terms of the extension, presentation and dissemination of this computer process, as long as the legal requirements are met, particularly those relative to the limits of pharmaceutical competence and the protection of named data.

It is not in the remit of the Order of Pharmacists to manufacture or certify software, the purchase of which is covered by private contracts by the terms of the personal practices of interested pharmacists. But it draws attention to the fact that it is the responsibility of pharmacists to request that service-providers offer and guarantee software including at least the functions outlined in the specifications, guaranteeing both the deontological and scientific development of the process and the presentation of the pharmaceutical opinion and the dossier in standardised format.

The specifications will be published in full in the Bulletin of the Order of Pharmacists along with a systematic commentary by the members of the working party having drawn them up.

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Summary of specifications
Pharmaceutical opinion and pharmacotherapeutic follow-up dossier

1 INTRODUCTION 1

1.1 Definitions 1

1.1.1 Pharmaceutical opinion 1

1.1.2 Pharmacotherapeutic follow-up dossier 1

1.2 General diagram of the process 1

(see appendix A)

1.3 Terminology 1

In the course of his intervention, the dispensing pharmacist may gather data from:

– the patient himself,

– a health care professional (physician, laboratory personnel, other pharmacist, nurse, physical therapist, podiatrist, etc.),

– a trusted person.

The quality of their entry and their source determines the level of detail of the analysis and the credibility of the PTFD.

1.3.1 Field 1

1.3.2 Data 1

1.3.3 Source 1

1.3.4 Numerical data 2

1.3.5 Auto number 2

1.3.6 Text data 2

1.3.7 Default data 2

1.3.8 Primary data resulting from a measurement 2

These data are entered, saved and can be used as is (weight, height pathology, etc.).

1.3.9 Secondary data resulting from a calculation 2

These data can be used only after manual or automatic processing.

This is the case for example of serum creatinine that requires the sex, age and weight of the patient to be entered in order to calculate creatinine clearance (Cockcroft formula).

1.3.10 Pro-active data 3

The parameters of these data that depend on the patient can be set by the pharmacist, are included in a drop-down menu and describe recommendations for prevention actions linked to a given disease.

1.3.11 Variable time-related data ---- 3
1.3.12 Data whose source must be identified to be validated ---- 4
1.3.13 Variable time-related data and whose source must be identified to be validated ---- 4
1.3.14 Active or passive data ---- 5
1.3.15 Target data ---- 5
1.3.16 Transmissible data ---- 5
1.3.17 Free text zone ---- 5

Text data entered in this zone contain written information that:

– Can be structured and via a set of automatic engines, could enable a system of alerts and detections linked to the database;

– Is text information with no current possibility of interconnection with the database, but may be necessary for the analysis of the pharmacist in his professional exercise.

1.3.17.1 Data from a validated evaluation grid ---- 6

There exist medically validated evaluation grids. They enable a code to be assigned to a situation in the absence of any clinical act. Examples:

–Fagerström test: evaluation of the pathogenic behaviour of a smoker;

– IADL (1) screening: test of dependence and autonomy;

–Baecke test(2): evaluation of physical activity, etc.

These are secondary data resulting from a score.

1.3.17.2 Data resulting from a professional consensus text ---- 6

There is a default proposal of a professional consensus text in this zone to assist the pharmacist in entry (elimination of natural language ambiguities, common vocabulary between the pharmacist and health care professional, etc.) and overcome the limited time generally according to dispensing.

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1.4 Functional restrictions 7
1.4.1 Initial entry ---- 7
1.4.2 Entry authors ---- 8

The PO is a formal explanation of an act that is the exclusive responsibility of the head pharmacist and/or his assistants.

The French Public Health Code clearly differentiates the respective competence of head pharmacists, assistants and interns.

Nevertheless and to the exclusion of all other persons, qualified assistants or 6th year pharmacy school interns exercising internships as legally defined, are certified to prepare this act under the authority of a pharmacist.

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A time counter determines the time required to prepare pharmaceutical opinions.
1.4.6 Order of screen appearance 9
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2.1 Administrative data 10

The pharmaceutical analysis of a demand for medicines, whether with a prescription or OTC, may lead to questioning the patient, the prescribing physician and sometimes the person picking up the prescription.

The administrative data used must enable an unambiguous identification of the subject, of the health care professionals involved, as well as the trusted person (picking up the prescription) acting for the patient. Most of these data are currently entered during the automatic (SESAM-VITALE® smart card) or manual establishment of a proxy payment.

2.1.1 Restrictions pertaining to the point of entry 10
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2.1.1.3 Personnel certified to deliver under the control of a pharmacist (preparation personnel, interns) 11
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2.1.2.1 Physicians 11
2.1.2.2 Other health care professionals 12
2.1.3 Concerning the patient 12
2.1.3.1 Patient 12
2.1.3.2 Profession of patient. 12
Certain medicines and certain precautions for use are by their very nature linked to professional activities or patient inactivity.

2.1.3.3 Trusted person [representative (s)] 13
The pharmacist is used to delivering products to a trusted person chosen by the patient, an intermediary ho has been authorized to accept the products.

The difficulty for the dispensing pharmacist involves the extent of the proxy that is generally informal and built around familial, emotional or social assistance relations. When the dispensing pharmacist cannot determine this and when dispensing requires either more information or that required to strictly comply with professional secrecy, as stipulated in articles R 5104-4 and after of the Public Health Code, the pharmacist (3) has the right to visit the patient's home.

The pharmacist decides on whether or not to enter the name and address of this trusted person, depending on the needs and level of confidentiality agreed upon with the patient.

2.1.4 Concerning veterinary pharmacy ---- 13
2.1.4.1 Identification of the animal's owner ---- 13
2.1.4.2 Identification of the animal ---- 13
2.2 Profile ---- 13

The entry of these variable data is indispensable for the automatic control of dosages and contraindications.

2.2.A Patient profile ---- 13
2.2.A.1 Variable pathology data ---- 13

The recording of diagnosed or presumed diseases is important for the detection of contra-indications, as well as the analysis of consistency of prescriptions.

2.2.A.1.1 General case ---- 13

The pharmacist is not the author of this information and it can be used only if the origins are precisely known. This indication of the source is fundamental:

– in the case of information gathered from a person different from the prescribing physician. It enables a disease diagnosed by a physician to be distinguished from one presumed by the patient or a third party;

– in the case of information deduced by the pharmacist from an analysis of the MA indications of products delivered during a given period (4) and enables:

- diseases and allergies to be recorded, as well as pregnancy and breast feeding that may dictate contraindications,

- or in some circumstances to eliminate these situations if the response is negative.

The date of onset of the disease can be entered for reasons involving its course.

In addition, the medical indications used by physicians, in the drafting of MA's or by other authorities (5) may be expressed differently. The aim of this is to enable the pharmacist to enter the name of the disease in recognized and unequivocal terms:

– by health care professionals;

– and by his interactions database so that it can trigger alerts (if they exist) depending on the patient profile.

These pathologies must be coded according to the reference thesaurus.

2.2.A.1.2 Special case of medical, personal and familial history ---- 14

The inclusion of personal and familial medical (and surgical) history is justified by the existence of certain contraindications in MA's.

2.2.A.1.3 Special case of hypersensitivity (allergy) ---- 15

The inclusion of known allergies can be very important for certain patients (intolerance to excipients having known effects, etc.).

2.2.A.1.4 Special case of pregnancy and breast feeding ---- 15

This information is indispensable for the early and automatic detection of the numerous contraindications related to these temporary states.

2.2.A.2 Variable physiological data ---- 16

Age, sex, weight, height, body surface, etc. of an individual are parameters used to control the dosage of certain medicines.

2.2.A.3 Variable biological data ---- 18

Input precision (unit, limit values, etc.), the date of the analysis and optionally the source condition the quality of monitoring risk factors.

2.2.A.4 Variable psychosocial data ---- 19

Data explaining the capacity of the patient to understand and comply with the treatment.

2.2.A.4.1 Psychological data ---- 19

2.2.A.4.2 Behavioural data ---- 20

2.2.A.4.3 Case of refusal of a medicine by the patient ---- 20

2.2.B Data concerning the animal ---- 20

In the case of dispensing veterinary medicines, data are not obligatorily required but they improve the quality of dispensing

2.2.B.1 Variable pathological data ---- 20

2.2.B.2 Variable physiological data ---- 21

2.2.B.3 Variable biological data ---- 21

2.3 Medicinal record 21

Recording deliveries and their future consultation are necessary for several reasons:

– The detection of potential interactions between several successive prescriptions that may be frequent in patients seeing several physicians, without the patient having necessarily provided each with all relevant information (forgot, embarrassed, etc.).

– Consideration of deliveries over a recent period, e.g. three months.

2.4 Monitoring risk factors 22

2.4.1 General principle ---- 22

When the pharmacist records a disease and it is inventoried in a list established by professional bodies, the system automatically triggers the Pharmaceutical Opinion process by ranking the data by treatment priorities according to the risk criteria corresponding to that disease.

3 PHARMACEUTICAL ANALYSIS 22

During the phase of analysis, the signing pharmacist, in addition to precise questioning, may implement any process of consultation and questioning on available information, using the possibilities of the management software and associated database.

3.1 Call for medicine 23

3.1.1 General aspects ---- 23

3.1.2 Economic aspects ---- 23

The pharmacist is legally required to participate in health care savings (6).

3.2 Alert from the medicine database 23

At the time of data input, alerts may be triggered by the mutual intersection of several prescription lines (interactions) or by the intersection between the properties of medicines and patient characteristics (contraindications or precautions for use concerning status (pregnancy) or the physiological (age, weight, height, etc.), biological and pathological profiles of the patient).

Alerts are generated by linking the demand with interaction databases currently available to physicians and pharmacists(7) (Vidal® dictionary, CBD(8), etc.).

3.2.1 Contraindications 23

3.2.2 Drug interactions [in a prescription(s) and/or concomitant or prior demand(s)] 24

3.2.3 Surveillance of dosages 24

The value of this procedure is a justified dosage adaptation.

3.2.3.1 General principle 24

3.2.3.2 Related to renal clearance 25

3.2.3.3 Related to the INR(9) 25

Treatment with AVK(10) must be very carefully followed since it exposes the patient to two principal risks:

– haemorrhage from an overdosage

–thrombosis from an underdosage.

Laboratory surveillance of AVK treatment is indispensable and is based on the Quick test expressed as INR(11).

3.2.3.4 Related to a measurable serum level 26

It may be useful to monitor the serum levels of certain medicines. In most cases, these medicines have narrow therapeutic margins and are administered chronically; e.g. anti-epileptics, digitalics, aminoside antibiotics, lithium, immunosuppressors…). These « non-systematic assays are conducted:

1. To control patient compliance;

2. When in spite of an apparently correct dosage, there are signs of therapeutic inefficacy or overdosage.

3. When there are concomitant medicines prescribed (or the concomitant absorption of non-medicinal substances) that could modify the pharmacokinetics of the active molecule.

When the medicine is prescribed for a kidney or liver failure patient and the molecule is eliminated and/or metabolised by these organs.

When the biological activity of the medicines can be easily quantified, it is of (practically) no use to assay them; attention is paid to the target effect (antidiabetics, anticoagulants, hypolipemiants…).

Aminoside antibiotics (amikacin, gentamycin, netilmycin, tobramycin) and vancomycin are often assayed but only in the hospital environment for « fine » and spot dosage adaptations.

The interpretation of immunosuppressor dosages (cyclosporin, tacrolimus) is reserved for specialised hospital departments.

3.2.3.5 Of a veterinary medicine 26

3.2.4 Medicines with a particular status 26

3.3 Nature of the problem 27

3.3.1 Problem typology 27

The analysis may reveal problems that could affect dispensing. Clearly identifying the nature of the problem in standardised terms ensures a high quality communication that must enable health the care professionals involved to react efficiently within useful time frames.

3.4 Therapeutic intent of the prescribing physician 27

In some clinical contexts, the prescribing physician may prescribe for unusual indications or with different dosages, and sometimes out of the scope of the indications or dosages defined by the MA of the medicine.

The pharmacist decides on the usefulness of determining the therapeutic intent of the prescribing physician.

3.5 Pharmaceutical argument(s) 27

This is the result of the analysis of data gathered by the pharmacist, according to the patient's profile, the nature of the problem and the therapeutic intent of the prescribing physician. The pharmaceutical argument justifies his decision.

The signing pharmacist remains the judge of the opportunity of formulating the pharmaceutical argument.

3.6 Proposal of the dispensing pharmacist 27

When justified by a problem detected or an opportunity, the pharmacist may propose a treatment modification to the physician.

4 DECISION 28

4.1 Formulation 28

The decision of the pharmacist is destined to be communicated to legally certified persons (in practice the prescribing physician).

4.2 References 28

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4.3.1.3 Declaration of a side effect of veterinary medicines 29

4.3.2 Advice 30

4.3.2.1 Specific advice 30

Pharmaceutical advice is a specific legal obligation. The pharmacist is not waived from this by information from the physician or by the instructions for using the medicine.

4.3.2.2 Following the therapeutic education of the patient ---- 30

The quality of therapeutic follow-up depends on the health education received by the patient. The effectiveness and relevance of the pharmacist's interventions in this area are based on their levels and their frequencies. Systematic and computerised monitoring enables a response to be obtained.

4.3.2.3 Following veterinary medicines: waiting period ---- 30

4.3.3 Notification ---- 31

For some classes or pharmaceutical forms of medicines, in the framework of therapeutic monitoring, or depending on the patient's own situations, in cooperation with the prescribing physician and/or with other health care professionals (in a network for example), it may be necessary to define the recipient(s) of the decision adopted (12).

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6 RECORDING A PHARMACEUTICAL OPINION 32

6.1 Payment number 32

Payment is a written trace of only delivery.

6.2 Recording a Pharmaceutical opinion 32

6.3 Cancelling a Pharmaceutical opinion 33

7 EDITING A PHARMACEUTICAL OPINION 33

Built around the decision, the standardised document includes (see appendix B):

– A zone for patient identification containing his administrative data, physiopathological characteristics and the nature(s) of the problem(s) encountered.

This zone corresponds to questioning the patient.

– A justification zone of the pharmacist that contains any of his proposal(s) and containing information explaining his decision, with the possibility of adding medical reasons having motivated the prescription.

– A zone for any advice given by the pharmacist, including (or not) information destined to the patient.

7.1 Prior to editing 33

7.2 Required items 33

7.3 Structure of the Pharmaceutical opinion 34

This is the standardised format intended to render the process and information immediately intelligible.

8 COMMUNICATION OF A PHARMACEUTICAL OPINION 34

This is based on two fundamental points:

1. It is covered by professional secrecy (art. R 5015-5 of the French Public Health Code and art. 226-13 of the (new) Penal Code). Its communication to unauthorised persons or companies, private or public, exposes its author and possibly the recipient, regardless of their function, to legal action, in particular penal.

2. Only the formal communication of the PO makes it legally questionable.

8.1 Internal consultation 34

Once each Pharmaceutical Opinion is validated it is stored. It is the reflection of the act accomplished and can be consulted by those having an access code.

8.2 External communication 35

The Pharmaceutical opinion is communicated:

I. When the pharmacist must do so:

- to the prescribing physician in case of refusal of delivery or a modification of the prescription(13);
- to the patient on his demand (14), with all the precautions imposed by the risk of interfering with the relationship with the prescribing physician;
- to legally or judicially certified authorities.

II. If the pharmacist decides it is a good idea:

- because the PO has a therapeutic value for the prescribing physician(15);
- because the PO clarifies responsibilities in case of a difference.

8.2.1 Prescribing physicians or health care professionals 35

8.2.2 Patient 35

8.2.3 Veterinary pharmacy: owner of the animal 36

8.2.4 Other (to state) 36

Personal data must be gathered, used and protected in compliance with existing legislation and the stipulations of the CNIL (data protection commission).

8.2.5 Mechanisms of communication 36

The head pharmacist(s) (and signing pharmacists in the course of their exercise) must take all necessary steps to protect the record and the computerized or manual consultation of PO's (process and data).

The mode of communication of the PO to health care professionals must provide all required guarantees of confidentiality and must ensure that it is received only by the exclusive recipient.

9 PHARMACOTHERAPEUTIC FOLLOW-UP DOSSIER (PTFD) 36

9.1 Description of a pharmacotherapeutic follow-up dossier 36

The Pharmacotherapeutic follow-up dossier contains all relevant and updated information gathered from prior pharmaceutical opinions.

This dossier assures a relevant follow-up if all data are classified by order of thematic priority and as a function of associated risk factors (pharmacotherapeutic follow-up dossier).

9.1.1 Constituting a pharmacotherapeutic follow-up dossier 37

9.1.1.1 Data from pharmaceutical opinions 37

9.1.1.2 Ranking of data 37

9.1.2 Recording and editing a pharmacotherapeutic follow-up dossier 37

9.1.3 Closing the pharmacotherapeutic follow-up dossier 38

This edition must comply with the same legal criteria as the edition of medical files when these criteria will have been established.

9.1.3.1 Patient deceased 38

9.1.3.2 Patient lost from sight 38

9.1.3.3 Effect of closure 38

9.2 Application: monitoring risk factors in non-insulin-dependent diabetes 38

The capacity of having a patient comply with a therapeutic project is ultimately just as important as the control of dosages, interactions, contraindications, etc.

This involves priority ranking of data whose surveillance is the follow-up of risk factors for patients with non-insulin-dependent diabetes.

9.2.1 Selection criterion 38

9.2.2 Patient profile 38

9.2.2.1 Physiological variables 38

9.2.2.2 Biological variables 39

9.2.2.3 Psychosocial variables 41

Among risk behaviours, smoking is always a major risk factor in diabetic patients because of the associated cardiovascular risks, multiplied by 6 in the smoking patient, while it is multiplied by 2.5 to 3 in non-smokers. It is essential to monitor this factor until this type of patient stops smoking.

9.2.3 Pro-active data of health surveillance 42

10 DATA EXTRACTION 42

The possibility of extracting and using relevant information, according to multiple criteria, aims at:

1. The security of medicinal treatment assured by the pharmacist in the framework of pharmacovigilance and of his participation in the fight against iatrogeny.

2. The assessment of medicinal treatment via pharmacological, epidemiological and economic analyses.

The collation and use of data are possible only in a legal context, and any agreements that are to be stated in compliance with the Ethics Code.

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10.3 Data on medicines purchased 44
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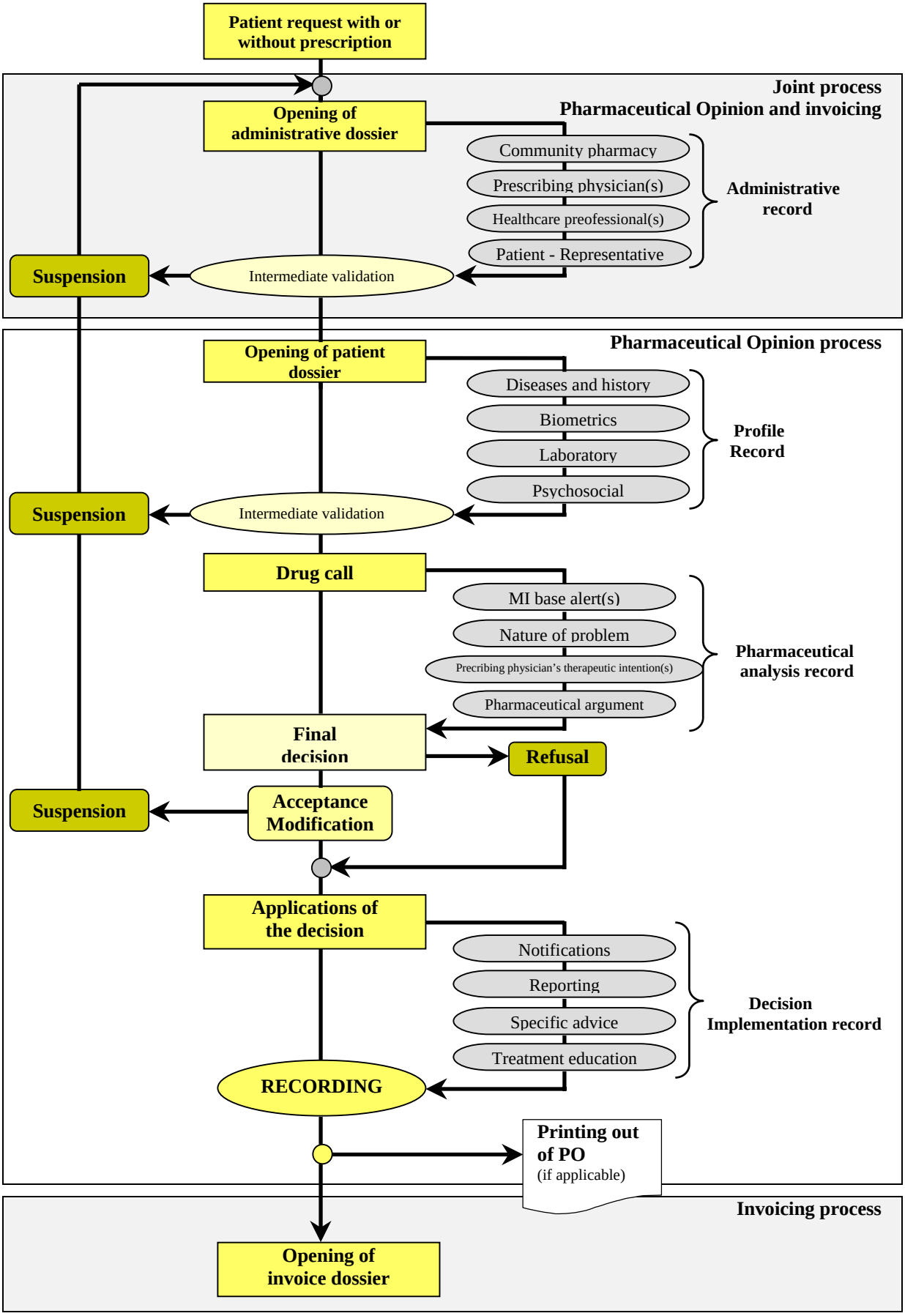
11.2 Concerning the monitoring of non-insulin-dependent diabetes 45
11.3 Concerning dosage monitoring that depend on special factors 45

(1) *Instrumental Activities of Daily Living.*
(2) Baecke *et al.* «A short questionnaire for the measurement of habitual physical activity in epidemiological studies ». *Am. J. Clin. Nutr.* 1982.
(3) Or his co-worker(s) legally authorised as cited in articles R 5104-4 and after.
(4) Entering data from the medicines database is done on the basis of therapeutic classes, indications, contraindications, precautions for use, side effects, interactions, pregnancy and breast feeding.
(5) CISSP: Classification Internationale des Soins de Santé Primaire (International Classification of Primary Health Care) for example.
(6) LFSS of December 27, 1998 granting pharmacists the right to substitute generic preparations or one of them and their original molecules.
(7) Or of their products (Officialis® Dexther®, etc.).
(8) Claude-Bernard Database®.
(9) *International Normalized Ratio.*
(10) Antivitamin K.
(11) Recommendations of the AFSSAPS (French Agency for the Sanitary Security of Health Products).
(12) Substantial modification of a dosage for an injectable medicine [physician and nurse].
(13) In the case of refusal or modification, or if the pharmacist judges it useful to explain precise information to the prescribing physician who may have need.
(14) Law of March 4, 2002 concerning the rights of patients and the quality of the health care system.
(15) Complex alert, a doubt removed or not, need for surveillance, original intervention, known vulnerability, pathogenic behaviour, specific precautions for use, particular substitution, etc.

Appendix A

General Flowchart of the process



Appendix B — Print-out format for a Pharmaceutical Opinion

l'Opinion Pharmaceutique

Internal identification field: ***(obligatory)***
Date/PO No. /pharmacotherapeutic follow-up dossier (PTFD) No.

Administrative identification field ***(obligatory)***

- **Pharmacist:** *Name, company name, address, phone/fax/e-mail,…*
- **Health care professional(s):** *Last, first names, specialty, code, address, tel, fax, e-mail*
- **Patient :** *Last, first names, address*

Patient profile ***(obligatory** when it exists)*:
Age, biometric and laboratory test data, psychosocial values

Nature of the problem ***(obligatory** when it exists)*: *Index*

Therapeutic intents of the prescribing physician: *free text zone*

Pharmaceutical arguments

- **Arguments :** *Free text zone*
- **Proposal :** *Free text zone*

Decision ***(obligatory)***: *Index*

Implementation of the decision

- **Notifications: (drug or device monitoring)** ***(obligatory** when it exists)*
- **Specific recommendations:** *free text zone*
- **Notification:** *recipient of the information (patient, physician, nurse, other health care professional)*

Transmission

- **Health care professional(s):** *Code*
- **Patient:**

Reference: *published works, databases, ministerial circulars, Public Health Code,…*

Signing pharmacist ***(obligatory)***: *Title, last, first names, Order of Pharmacists No.*