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The Pharmaceutical Act

Legal considerations for an intellectual and ethical redefinition

This article reiterates the analyses that the author presented in preceding publications and developed at lectures concerning “pharmaceutical opinion”, the quality assurance instrument of which the pharmaceutical act is the legal basis⁽¹⁾.

The expression “pharmaceutical act” is often used and often criticized without a clear understanding of its meaning and its legal scope (2). If we are to believe public debate, the lack of interest in the doctrine and a simple, linear reading of the texts, the modern “*pharmaceutical act*” seems to be simply a fantasy.

But an analytical reading of the Public Health Code and the jurisprudence allowed us to conceptualise the pharmaceutical act and to confirm the rationality of the notion and the legitimacy of its use. This notion is a key to understanding the texts and a prism for a new, future-oriented reading of them: it can lead the way to an in-depth reflection on the future of pharmacy and the organisation of our health care system, even beyond the national scale.

After an introduction demonstrating the ambiguity of the usual terms used for discussion, we will take a practical look at the notion and the legal framework of the pharmaceutical act, while offering some orientations for interdisciplinary consideration.

The pharmaceutical act, the historical basis of the monopoly

The fabrication of drugs is a dangerous activity. Historically, this justified the establishment of a monopoly for apothecaries and then maintaining it when the great Turgot sought to free the French economy from the paralysis of the corporations: the monopoly then found an indisputable rational, scientific – rather than ideological - basis (3).

For this reason, drugs and the monopoly were long seen as being consubstantial. This can be seen in the first legal definition of drugs in 1941. They received distinct legal definitions in 1959 (4).

The industrialisation of drug manufacturing led to a dissociation of these activities, and of the concepts behind them. At community pharmacies, the nature of the pharmaceutical act progressively changed from fabricating to dispensing drugs.

* The opinions expressed here are personal (megerlinf@hotmail.com) and do not in any way reflect those of the Commissions to which the author belongs.

The disappearance of the original pharmaceutical act

What is the purpose of the community pharmacist? We start to have doubts regarding the nature of his activity, doubts that increase rapidly as the pharmacist moves further away (materially, and then legally) from the manufacturing of drugs (5).

With the disappearance of the original pharmaceutical act, and progressively stripped of its *objective* rational justification, the monopoly “*of skills*” of the pharmacist is then systematically under attack in theoretical terms and, gradually, in practical terms.

Attention focused on the legal notion of drugs

All the attention remains focused on the legal notion of drugs, the basis of pharmaceutical law: it defines the contours of the monopoly and protects its substance. The term “*drug*” thus crystallises doctrinal thinking, professional interests and strategic thinking.

But while it determines *the extent* of the monopoly, the legal notion of drugs is powerless to establish its *basis*. For the technical and legal reasons mentioned, this basis is no longer self-evident.

It is stressed that community pharmacists now have a major role in the protection of public health, essentially through their function of checking requests for drugs (prescribed or recommended).

The controversies in this regard are sometimes violent (6), and all of the figures of the system claim to be protecting public health, making this seem almost like an alibi (7). Also, pharmacists sometimes seem to be looking for a social justification: we see services that developed in the suburbs around a business centre that was apparently enucleated.

Lastly and above all, a vocabulary borrowed from trade has become mixed in with the legislative part of the Public Health Code.

The semantic confusion: dispensing/selling

While the Public Health Code is clear in the distinction between the fabrication and the sale of drugs, it seems confused in the distinction between the notions of sale and dispensing: they are practically synonymous! This raises questions about the meaning and the scope of article L. 4211-1 (former L. 512), which created the monopoly, restricting “*dispensing*” to pharmacists.

The confusion is obvious in the legislative part of the Code. In part V, within volume I “*pharmaceutical products*”, there is a chapter V entitled “*wholesale manufacturing and sale*”, then a chapter V, entitled “*retail sales*”... Community pharmacies are defined by article L. 5125-1 as “*establishments for the retail dispensing of drugs*”...

The confusion also seems to be present in the regulatory part of the Code, which contains the definition of dispensing. Article R. 5015-48 does define dispensing as a specific process of analysis, preparation and advising. But its wording suggests to the neophyte that the issuing of drugs is the necessary conclusion of the process (8), as if all requests had to be fulfilled.

These are only emblematic articles among many other examples. The confusion of these notions points to a *theoretical* absence of autonomy (legal, professional, ethical) in thinking on this point.

In the terms provided for public debate, the logical consequence of it is inescapable: the intellectual condemnation – and thus the legal elimination – of this unjustified exception to common law.

Community pharmacists, victims of appearances?

Despite the depth of their professional code of ethics, the activity of pharmacists is often *reduced to a health service dominated by a commercial appearance*. The beneficiaries and all of the figures in the health care system are then caught in a vicious circle: it is formed by the techniques for promoting drugs, the appearance of the community pharmacy, by the system for remuneration of the pharmacist, and by the behaviour of some patients and some practitioners. This circle limits, stirs up and obscures a debate that has become urgent and difficult with the financing and organisational problems of our health care system.

Within this debate, the social and public health importance of community pharmacists is exalted (supply, control, advice, teaching, prevention, data gathering, alerts, etc.); and it is legitimate to say that this is based on the quality of their scientific knowledge and on their geographic coverage.

But because of the above-mentioned points, lawyers who are in a hurry and ever more critical observers have trouble seeing a justification for the independent, personal and monopolistic nature of this business. The pharmacist's residual action, his shift towards sales, and his apparent subordination also deprive him of scientific authority, which should logically be that of the final decision-maker for the health care, while the legal debate on the issue of substitution reminded us of the essence of the respective roles of health care professionals (9).

Although EU competition law does not require in-depth justification of national monopolies (as long as they do not lead to discrimination), this justification is becoming more and more necessary domestically, in France especially. And, if one is not found, the atrophy or disappearance of the monopoly – however painful it may be – will not seem scandalous to us.

Community pharmacies are in fact at the heart of an epistemological transformation

For all of these reasons, pharmacists must certainly be feeling that they are in the eye of the cyclone. But aren't they in fact at the heart of an epistemological transformation? We can borrow an illustration from Teilhard de Chardin in this regard: sometimes "*we believe that we are going through a storm; in fact, we change climates*." The storm that pharmacists have been going through for several years now is well-known (10). Many even see the Flood coming in which, with their monopoly lost, they would be drowned.

The new climate (scientific, social, technological, economic, judiciary, etc.) is only hinted at. It will involve a rediscovery of the profession, using instruments based on professional ethics, not on weather reports...

Community pharmacists must break free of their historical intellectual universe, like many other professions and institutions at the beginning of this 21st century.

The essential activity of pharmacists is no longer the fabrication of drugs, nor sales, but rather *dispensing* (articles L. 4211-1 and R. 5015-48).

But what are the nature and the extent of the responsibilities involved? Can dispensing really be seen as an act with the dignity of a medical act? Can its scientific specificity be a rational basis for a legal monopoly?

These are questions that lead us on to ground that differs from that of the legal notion of drugs. As a linear reading of the texts does not allow us to answer these questions, a comparative analysis is required.

The focus is too often placed solely on advice, although this is only the tip of the iceberg. Personalised advice is also to be found in sales situations, as a marketing tool. It is the decision-making responsibility of the pharmacist that gives dispensing its legal characteristics.

We have thus demonstrated that dispensing designates in essence an *autonomous analysis and decision-making process*, for which the pharmacist bears the original scientific and legal responsibility - personal and irreducible - with respect to the doctor and the patient (11).

The 1995 reform of the Code of professional ethics seems to us to have laid the foundations for a new way of thinking. With this reform, the notion of pharmaceutical act underlies the Code of professional ethics, even though its constitutive legal elements are dispersed within the various sections and parts.

Analysis of the texts and the jurisprudence (of which we will spare the reader here, presenting only our conclusions), allows us to conceptualise the pharmaceutical act, the only rational link between the drug and the pharmacist's shop. We will examine the notion (I), then the legal framework (II).

I. The notion of pharmaceutical act

If we reason simultaneously based on all of the provisions of the Public Health Code, we can say that a basis for the monopoly has been found again: *it is because there is now the need for a decision* that there is a professional exclusivity, the obligations of independence and personal activity, etc., of the pharmacist, which aims to guaranty his scientific competency and his integrity.

Dispensing is indeed the name given to the pharmaceutical act; but dispensing and issuing are too often confused. These two notions must be carefully distinguished, and their intellectual interlinking must be clearly established. The fundamental aspects of dispensing are poorly understood: the obligation of analysis (A) and the power to decide (B).

I.A. The obligation of analysis

As the act is invisible, silent and remunerated by a sales margin, the nature and extent of the analyses required by the Code when drugs are requested (prescribed or recommended), remain poorly known. In order to define this obligation of analysis, we must compare its various facets (1), before mentioning the purpose (2).

I.A.1. Typology of the analyses

With the term "*pharmaceutical analysis*," article R. 5015-48 enjoins pharmacists to analyse the *contents* of the request (a). But a systematic examination of the articles of the Code disseminated in other sections or parts shows that dispensing also covers, implicitly but necessarily, the analysis of the *context* of the request (b).

a. Pharmaceutical analysis of the content of the request

Article R. 5015-48 requires an intrinsic analysis of the request. This analysis, if it is to be legally comprehensive, covers several processes mentioned in other articles. In summary, these are:

- the regulatory analysis of the request*, which aims to verify that the prescription is authentic, proper and legal, in terms of its author, form and content;
- the pharmacological analysis of the request*, which aims to detect any possible drug interactions, contra-indicated associations, etc.;
- the economic analysis of the request*, introduced in 1998, which simply means consideration of the possibility of substitution (article L. 5125-23, etc.).

The first two analyses essentially involve an obligation of results, as they use objective data. The last analysis however calls for additional thinking, extended to the personal context of the request: the appropriateness of the substitution also depends on the capacity of the *patient* to understand it.

b. Pharmaceutical analysis of the context of the request

This second series of analyses is not defined in article R. 5015-48, but the Public Health Code expressly makes the pharmacist the guardian of the "*interest of the patient's health*." The consideration of this interest is the basis, as we will see, for the refusal of issuing (article R. 5015-60, section IV) (12), and the possibility of concerted modification of the prescription (article L. 5125-23 which replaced article R. 5015-61) (13).

This establishes the principal of analysis of the personal context, even though the formulation of it is fragmentary, and its extent is not determined. Concretely, the “*interest of the patient*” can only be evaluated through:

- *evaluation of the physiopathological context of the request*, which includes checking of the dosage, detection of contra-indications, possible allergies and hypersensitivities, establishment of precautions for use, etc.;
- *analysis of the drug context of the request*, which covers the detection of risks of interactions, contra-indicated associations, etc. with other treatments, chronic or not, prescribed or not;
- *evaluation of the psychological context of the request*, which simply involves checking the patient’s intellectual aptitude to understand, administer and observe a treatment, prescribed or not, substituted or not.

The dispensing process is in consequence sometimes suspended while awaiting information (additional element, medical argument, result of laboratory analysis, etc.) to determine the pharmacist’s conviction, or requiring further thought. These fundamental obligations represent, because of their subject and the conditions for carrying them out, an obligation of means; they lead to sophisticated ethical considerations that remain little examined.

I.A.2. The purpose of the analyses

“*Participation in the protection of public health*” is at the heart of the community pharmacist’s mission (14). But what – concretely – is the “*patient’s interest*”? This question is fundamental, because it focuses on the *purpose*, and not just the modalities of dispensing. Various responses are possible depending on individual practice. Dispensing is often seen in a minimal definition: making sure that the drug care is safe (a) – although it could and should in the future include its appraisal (b) (15).

a. The safety of drug care

By care safety, we generally mean the spot-checking of drug requests (prescribed or recommended), using penal criteria for *endangering*.

At the community pharmacy, the gathering of information is often limited by practical difficulties (availability, confidentiality, etc.) or, sometimes, psychological difficulties (lack of understanding and touchiness), because this collection is done only with:

- *the medical prescription*, the analysis of which reveals the therapeutic indications, but these indications are not sufficient to assume a given illness;
- *questioning of the patient*, but the reliability of the information is not certain, the person representing the patient is not always (and shouldn’t necessarily be) aware of his situation;
- *possible questioning of the health professionals involved*, in order to obtain or to confirm the above-mentioned information, with secrecy applied in the interest of the patient.

While it is perfectly justified and thus explainable, this conception of drug care safety “*at first glance*” appears to us rather limited: it suggests that the professional’s activity is based solely on the Penal Code, which seems to limit the pharmaceutical thinking, leading to a legal explanation of the monopoly that we do not completely share (16). Also, the safety role, while essential, is evolving: the safety of drug care must, more and more, involve a contextual (physiopathological and drug environment) approach, not just an isolated approach (intrinsic analysis of the prescription) (17).

But “*the patient’s interest*” is not limited to protection from imminent danger: even if reduced to the issue of safety, it extends to prevention of multiple causes of iatrogenicity, of which we know the human and economic consequences. In the paradoxical absence of explicit legal texts concerning community pharmacies - although they are soon to appear for hospitals (18) - the enlargement of the pharmaceutical analysis thus varies considerably, depending on the circumstances of the dispensing and according to the consciousness of practitioners.

But only a change in the conditions of the act (space, time, consideration, remuneration) could lead to a change in this minimalist conception of dispensing, which is far below the scientific capacities of the pharmacist and the real needs of public health.

b. Appraisal of drug care

The protection of public health can have a broader legal meaning based on “*the interest of the patient*”: optimising drug treatment. Beyond the mere issue of safety, there is a function of *appraisal* of the care, provided by the pharmacist in cooperation with the doctor, in virtual liaison with other professionals (laboratory pharmacist, etc.). This cooperation is based on the complementarity of their respective scientific skills and on their mutual trust, possibly developed within appropriate procedural frameworks. It may also go beyond the challenge of stricter safety to examine the pharmacological aptness (or technical modalities) of the drug treatment.

While the information involved at first seems sufficient for the prevention of serious risks, it is no longer sufficient here; but the introduction of pharmacotherapeutic monitoring can remedy this. The appraisal would then involve an in-depth analysis and concerted management by the various independent practitioners (and possibly in conjunction with the hospital) of the drug strategies in terms of their intention, contents and context. In terms of strict safety criteria of course, but also criteria for quality, efficacy, comfort and economy of the drug care, allowing for its evaluation/adaptation/orientation by taking into account *the specific characteristics of the patient* – and not a regulatory, financial or therapeutic standard.

Based on cooperation through a network, this process (which supposes greater recognition of the pharmaceutical act), announces the coming of clinical pharmacy. It calls for a profound renewal of legal, ethical and pharmacoeconomic thinking.

I.B. The power to decide

Based on these analyses, the Public Health Code gave the pharmacist real decision-making power: dispensing does not always lead to issuing. An analytical reading of the Code helps us to fit together the various decisions, and to stress the rational unity of their source (1). Based on the analyses mentioned, the decision made by the pharmacist determines the accomplishment of the rest of his obligations (2).

I.B.1. Typology of the pharmacist's decisions

Without ruling out the hypotheses of manufacturing, preparation, and conservation defects, etc. of the drug at the community pharmacy, the penal, civil and disciplinary responsibility of the pharmacist now comes essentially from his *decisions* – that may result from flawed analyses, lead to a substitution error, to incomplete advice, etc. (a). But the statistically more frequent decisions must not overshadow the other hypotheses (b).

a. Typical decisions

The issuing of a drug or a product (article R. 5015-48) is certainly an action; but, legally speaking, it materialises a decision. In the logic of the Public Health Code, issuing supposes that the analyses mentioned are conclusive, and that all doubts have been removed.

Invoicing of drugs (prescribed or recommended) constitutes an implicit validation of their request; it engages the pharmacist's responsibility in this regard: it is in a sense through the intellectual prism of *the prejudicial act* (and not simply through the prism of the prejudicial fact) that professional rules and civil and penal law must be sanctioned.

Deferment of issuing is also a decision in itself, because of its potential therapeutic consequences. It covers another typical hypothesis: that of suspension of the process while awaiting determining information (additional element, medical argument, result of a laboratory analysis, etc.) to remove a doubt, or on the contrary requiring further reflection. Though formally absent from the Code, this hypothesis can be inferred from article L. 5125-23.

b. Exceptional decisions

The relative rarity – and the habitual discretion– of these hypotheses should not mislead the patient, the prescribing physician, or the pharmacist himself. They are derived from a fundamental obligation and constitute the very skeleton of the independent and monopolistic nature of the profession.

Concerted modification of prescriptions is quite frequent, but it is expressed in the texts in a way that seems inhibiting. Also, this hypothesis has left the Code of professional ethics (R. 5015-61), and now appears in the legislative part (L. 5125-23). It seems to us however to be the bedrock of the community pharmacist's initiative, the quintessence of his present and future role: offering the prescribing physician a medicinal alternative, based on his scientific know-how (correcting a material error, or adapting a treatment based on pharmacological or technical criteria) (19).

Automatic modification is motivated by the interest of the patient's health, urgency and the impossibility of contacting the prescribing physician (L. 5125-23). While this situation has become very rare since the law of 1998 on substitution, it is still a sensitive issue. We can prudently link it to the issue of automatic dispensing, based on the obligation of assisting persons in danger; but the debate is far from being closed (20).

Refusal of issuing (R. 5015-60).

when faced with "*dangerous*" issuing, is the most radical expression of the pharmacist's responsibilities with regard to the patient and to the prescribing physician. This decision can lead to conflictual relations, in the event of an inappropriate motivation, or inappropriate sensitivities. But, as we will see, it is indeed through its legal framework that the independent essence of the pharmaceutical act - the only modern justification for the monopoly of community pharmacies - is asserted.

I.B.2. The execution of the pharmacist's decisions

In legal terms, the pharmacist is considered to be the author of the acts carried out at his pharmacy, by the terms of his obligation of personal practice – establishing the basis for the supervision of his co-workers with regard to delegated work (R. 5015-13). The act is thus extended by the possible preparation (a), and doesn't end until after the giving of advice (b).

a. Preparation

No particular reflection is called for here. Only the new role of preparers deserves a brief comment: in addition to their usual tasks, they are now mostly involved in the preparation and carrying out of decisions (prior measures, mobilisation and entry of certain data, administrative, accounting aspects, general advice, etc.). But the decision, its possible justification, etc. are solely the pharmacist's responsibility. The tasks are delegated by the pharmacist(s) depending on the internal organisation of the community pharmacy, in observance of the competency criteria of the Public Health Code. The clarity of and observance of this code establishes the pharmacist's scientific authority with regard to the beneficiaries, actors and observers of the health system.

b. Advising

This is an integral part of the act and is easier to objectify than the "*obligation of support*". The obligation of advising the patient is unquestionably a *legal obligation*. This obligation is reinforced when the drug is not prescribed (R. 5015-48). The absence of a prescription does not make the patient a consumer, nor the drug a product. But the reality of "*appropriate*" advice and participation in "*support*", in the sense of article R. 5015-48, depends on the pharmaceutical analysis of the content and the personal context of the request. Failing this the advice is "*within the reach of any shopkeeper who knows how to read and write.*"

Let us note that the obligation of personalised advice is an *autonomous obligation*, and this is fundamental: the pharmacist is not freed of this obligation by the prior advice given by the doctor, nor by the information in the instructions for use of the drug or product. Lastly, if particular advice is to be given, it will probably, more and more frequently, have to be proven (21). This is also a matter for professional and ethical thinking, and a relative analogy with medical thinking does not seem artificial.

With the general nature of the pharmaceutical act thus briefly established – and potentially revealed by the *pharmaceutical opinion* – we can turn our attention to the legal framework.

II. The legal framework of the pharmaceutical act

While the preceding is easily intelligible (what pharmacist has not experienced such situations, even if he didn't perceive their significance or legal coherence?!), what follows is a bit more abstract, but just as fundamental. The remuneration of an independent intellectual process *by a commercial margin on the sale of a product* hinders the understanding of the act, and sometimes even taints the practice. The pharmaceutical act has a real autonomy (A), of which we will briefly examine the legal scope (B).

II.A. The autonomy of the pharmaceutical act

The idea of the *hierarchical* subordination of the pharmacist is historically explicable, but now anachronistic given the changes in the act (from the fabrication to the dispensing of the drug). The modern pharmaceutical act carries with it an original scientific responsibility that is legally irreducible. *This* is what establishes the obligation of independence and of the personal and monopolistic running of community pharmacies.

Etymologically, “*autonomy*” means the capacity to be governed by one's own rules, or obeying one's own rules. This autonomy, legal *because it is* scientific, means that the pharmaceutical act is not subordinated, neither hierarchically (1), nor ethically (2).

II.A.1. The legal autonomy of the pharmaceutical act

In legal terms, what fundamentally distinguishes the pharmaceutical act from a service of a commercial nature is the exercising of the *refusal* (in logical terms it is of no importance that this hypothesis is exceptional).

While the obligation of refusal was only recently instituted explicitly (a), it has considerable importance for understanding the role of the community pharmacist (b).

a. The establishment of the obligation of refusal

With the reform of 1995, the formulation of the obligation of refusal of dangerous issuing is very clear (R. 5015-60). It clearly shows the historical shift in the role of the community pharmacy (from fabrication to dispensing), and thus illustrates the change of professional paradigm (from material service to intellectual service) that we evoked. Its consecration in the texts may seem tardy, but it is very welcome after, as Professor Georges Viala notes... “*27 years of gestation*”! It was this article, in 1995, that revealed the *decision-making* responsibility of the pharmacist.

The basis for the obligation of refusal merits reflection. Unlike the classical doctrine, it seems to us that this obligation is not based on a mere projection of the requirements of penal law in the Code of professional ethics. The intellectual roots of the refusal require a deeper view, even though, until now, they were not conceptualised in this way: it is because he *alone* has the scientific competency that allows him to analyse and to be able to refuse if necessary that the dispensing monopoly is reserved for the pharmacist. His decision-making responsibility is not, in our opinion, the “*compensation*” of the monopoly, it is its very *foundation* (22). This is essential for the understanding and preserving the independent nature of the community pharmacy.

b. The scope of the obligation of refusal

This fundamental clarification stems from some jurisprudence from even before the reform. The State Council, in particular, judged in 1994 that “*while the provisions of the (former) article R. 5015-45 of the Public Health Code enjoin pharmacists not to modify prescriptions without the prior and express agreement of their authors, this rule does not absolve the pharmacist of seeking such an agreement (in the event of danger) and does not exonerate him from his responsibility when this agreement is not obtained*” (23). Thus, the confirmation of the prescription by the doctor does not free the pharmacist of his own obligations; he bears the original, final and irreducible responsibility for his acts (24).

This again seems essential to us because the inverse would mean *a contrario* a state of subordination that denies (and thus condemns) the independent nature of the pharmacist: if we accepted the thesis of submission to the argument of

authority, we would logically have to recognise that the real scientific competence lies solely with the final decision-maker (see below). In that case, we don't see what could define the monopoly "*of skills*" of the community pharmacist. This line of jurisprudence is the juridical and ethical keystone of the system. The pharmacist should be proud of this intellectual strictness, and shouldn't be offended.

II.A.2. The ethical autonomy of the pharmaceutical act

The scientific and legal autonomy of the act then imply its ethical autonomy, or the requirement of individual, in-depth reflection, which must go beyond the formal frameworks and mechanical constraints of the practice, in the name of its humanistic vocation.

a. The unity of the obligations

At the hospital, the quality of the organically-integrated, joint and continuous monitoring of the patient, certainly leads us to formulate the obligations of the hospital pharmacist in a way that, in terms of regulations, *does not indicate the possibility of a refusal* (25). But the variations between the material, textual and statutory conditions of private and hospital practice must not obscure the profound unity of the professional ethics of pharmacists. The refusal of issuing of drugs should not be just a discreetly hidden hypothesis, because it is professionally feared: it is potentially as vital at hospitals as in community pharmacies, even if, in practice, the issue rarely arises (26).

While the hypothesis of a refusal is exceptional *at a community pharmacy*, let us recall that the injunction ("*I say*") or the confirmation of the prescription by the doctor does not free the pharmacist from his own legal responsibility. We offer an additional key to understanding the pharmaceutical act: while the jurisprudence distributes these responsibilities in the event of prejudicial issuing following confirmation of a dangerous prescription, it is because the pharmacist – who has an irreducible decision-making responsibility linked to his exclusive scientific qualification – *is considered to have been convinced by the medical argument*. In legal terms, we can thus consider that there was a therapeutic agreement, after a risk/benefit analysis in which the respective competencies were exhausted... unless, in less complex hypotheses, there is simply shared negligence.

b. The requirement of reflection

All of the preceding seems to sufficiently demonstrate that, in scientific, legal and ethical terms, the pharmacist is not reduced the role of an executing agent: he has an obligation and a legitimacy in the therapeutic reflection; he has the competency, the power and the final responsibility for his decision. It is also in this regard that his initial training at the university and his continuing education at the community pharmacy should allow him to develop the pharmaceutical act (and thus the pharmaceutical opinion); but this latter debate is more of a professional (quality assurance debate) and university education issue rather than one for legal reflection (27).

That being said, the current configuration of the system (role of community pharmacists not always understood, remuneration system rather degrading, difficult relations with some health professionals, etc.) still inhibits this action. *But this has no influence on the legal responsibility of the pharmacist*. And above all this must not inhibit his reflection, which is imposed by the transformation of the conditions of medical practice, and which will encourage the arrival of new technologies in the service of clinical pharmacy. The continuous development of means leads to two inescapable corollaries: in legal terms, ever stricter safety obligations; in professional terms, development of the potential for appraisal.

II.B. The scope of the autonomy of the pharmaceutical act

With the meaning of the autonomy of the pharmaceutical act thus explained, we will mention (very briefly) its practical scope, with regard to the patient (2) and to the prescribing physician (1).

II.B.1. The autonomy of the pharmaceutical act with regard to the prescribing physician

As we saw, the refusal of issuing is a pivot for juridical reflection. But it is nonetheless a rather exceptional decision: the refusal is normally preceded, and ideally avoided, by joint reflection by the pharmacist and the doctor. This leads us to think more concretely about the meaning (a) and the development (b) of their obligations.

a. The meaning of the obligations

Faced with a medical prescription or a patient's request, the community pharmacist's action is not binary (yes/no). The causes of a refusal of issuing – and sometimes even a simple deferment of issuing – are necessarily serious; the psychological and therapeutic impact, or even professional impact, is potentially high. The decision must then be duly and rigorously justified, and preceded by a confidential, courteous and in-depth examination with the doctor(s). This reflection may then lead to the concerted modification of the prescription, in the interest of the safety of drug care (correction of a material error, etc.), or even its appraisal (pharmacological or technical arrangement of a treatment). We indicated our great regret regarding the recent modification of the Public Health Code on this subject (28).

The pharmacist then can and must supply the useful information (or even sometimes proposals) to the prescribing physician, depending on the quality of his relations with him. He must be able to take advantage of his therapeutic and diagnostic actions. This brings up the issue of broader concertation, when the pharmacist finds himself at the crossroads of the acts of various professionals to whom he must guarantee confidentiality, respecting the patient's freedom of choice of his practitioners. This raises the issue of shared secrets, when the information sought is determining for the dispensing (29). It is surprising then that there are no *common standards of professional ethics* between doctors and pharmacists on this subject.

b. The development of obligations

The transformation of the historical role of community pharmacists has a profound significance, still poorly understood, within the therapeutic chain itself. It can thus sometimes provoke fears and inappropriate sensitiveness if the scientific responsibilities (i.e. the rational basis of legal monopolies) are not *explicit and understood*, or if they are poorly handled. Beyond the thinking of professionals in terms of professional ethics and standards, public authorities should also provide clear texts to encourage and recognise therapeutic cooperation in this direction.

This is strongly in doctors' interests: this cooperation makes the prescription and the dispensing processes safer and stricter. It also opens up new possibilities (prevention of iatrogenic risk, setting up, evaluation and orientation of drug strategies, monitoring of formerly hospitalised patients, drug epidemiology, etc.).

Lastly, while practitioners are now finding greater solidarity to confront the scientific and regulatory complexity of their practices, this is also occurring because of the threat of litigation. While sometimes on the fringe of rationality, this latter factor can only further encourage therapeutic cooperation, if pharmacists and doctors are not spontaneously led to this by their ethical reflection. But – and this is still fundamental – their *joint* ethical reflection is needed *at the earliest stage*, if we want to avoid inappropriate solutions (legal, regulatory, jurisprudential), that naturally stir up public passions and obscure the debate.

II.B.2. The autonomy of the pharmaceutical act with regard to the patient

This is also a very sensitive dimension of this issue, discussed here only in broad terms. Although it is paradoxically remunerated by a sales margin, the pharmaceutical act should, to the extent possible (b), be autonomous with respect to the patient (a).

a. The meaning of autonomy

In legal and professional ethics terms, the pharmaceutical act is the same, *whether the drug is prescribed or not*: the dispensing certainly varies in its material conditions, but it is invariable in its intellectual requirements. Failing this, the monopoly would seem to us unjustified for drugs, which the absence of an act would then put on the same level as normal consumer products. In legal terms, there is then a fundamental unity of the act, the depth of which depends

only on the pharmacist's personal practice. His professional ethics are again demanding: in practice, we know that professional consciences are unequally scrupulous, and that patients are often impatient...

In any case, the will of the patient or his representative *in no event* frees the pharmacist from his legal obligations, his monopoly aiming precisely to ensure his scientific competency and his independence of spirit. Even if the patient is insistent, this does not in any way offer exoneration in a case that puts the patient in danger, and/or with regard to preservation of public health (R. 5015-10). If the problem is less severe, we can recognise that this patient's will has some role. But on condition that a patient who is capable of it is duly informed of the risk that he runs; this once again raises issues that are sometimes very delicate by nature, namely the extent and proof of pharmaceutical information given to the patient (30).

b. The limits of autonomy

The obligation of evaluation of the personal context (physiopathological, medicinal) of the prescription or the request requires the mobilisation of the appropriate data particularly, as mentioned, through questioning. This makes the patient's contribution to the dispensing irreducible, and potentially determining. But he must convince himself of this – i.e., *or he must be convinced*.

Obtaining this information is not always easy: as the independence of pharmacists is not explained and sometimes not accepted, is often poorly understood; it is also inhibited by constraints of a material nature (time, space), and sometimes of a legal nature (patient's consent, confidentiality with representative) or even psychological (reticence of some patients and health professionals) – without mentioning the economic aspects. But the conditions and the perception of the practice could change profoundly with the establishment of pharmacotherapeutic monitoring.

The result of all of these ambiguities and the frequent ambivalence (patient/consumer) of patients is a source of serious health risks and intellectual confusion. We know of this because of the new threat of heated – or even massive – litigation that hangs over the heads of practitioners and the drug industry. But before this, this confusion interferes with the understanding, acceptance, observance and evaluation of drug treatments (without mentioning respect for the value of acts and substances), and brings with it human, epidemiological and economic consequences that threaten the equilibrium of our system itself.

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Thus conceptualised, the pharmaceutical act seems to us to answer the question of the rational (and not just historical) basis of the rules of the Public Health Code. It allows us to rediscover their logical unity and invites us to reconsider the approach to many essential issues. It opens up unexplored possibilities that could be extrapolated to hospitals and that could be of value for the entire health care system.

Aren't awareness and teaching of the legal dimension of the act vital *within, and beyond* the therapeutic chain? For this, it will probably be necessary to explain the pharmaceutical act – by taking a new look at the structure of the Code and sometimes the wording of the rules (31) – but also by deepening it and using it (32). This opens another debate that is no longer legal but rather professional or university-oriented.

Failing a comprehensive vision freed of excessive technical points for these issues, the beneficiaries, actors and observers of the health care system will remain legitimately unsatisfied. Their doubts, serious and simple, will continue to turn towards penal and civil law, and to commercial, competition and consumption law. It is now essential that the reflection be removed from these fields to which the dominant thinking has progressively reduced it, and in which it is inexorably being atrophied.

While the ambiguity of the role of the community pharmacist shakes his faith, affects his interests and his future, it also condemns his intellectual ambition and his ethical reflection. By extension, it threatens the future of university teaching and scientific research. But it also provokes, inescapably, the extension of the responsibility of industry, and complicates the practice of medicine. Lastly, and in a more diffuse but absolutely fundamental manner, it challenges our humanistic conception of the patient.

Notes

1. F. Megerlin, «*L'autonomie de l'acte pharmaceutique. Vers une réforme du Code de déontologie?*», *Rev. dr. san. soc.* 2000, 746; «*L'opinion pharmaceutique. Une révolution à l'officine*», *Rev. dr. san. soc.* 1998, 665; partly reprinted under the title «*De la sécurité à l'expertise du soin?*», in *Bull. Ordre pharm.* 1999, 465, etc.
2. The texts do mention a «*pharmaceutical act*», and the “*act of dispensing drugs*”, but without specifying exactly what this involves or the legal framework.
3. V. C. Maurain and M. Bélanger, «*Le droit pharmaceutique*», and E. Fouassier, «*La notion de base du droit pharmaceutique: le médicament*», *Droit pharmaceutique*, Litec 2000.
4. Law of 11 September 1941 (former article L. 511) and the order of 4 February 1959 (modifying the former article L. 511 and introducing the former article L. 512).
5. Thus, law n° 80-512 of 7 July 1980 (the so-called Talon law) forbids the unpacking of drugs on the list of dangerous substances for their use in mixed preparations (article L. 1342 -3), etc.
6. «*Quatre-vingt pour cent des pharmaciens ne contrôlent pas les ordonnances*», UFC-*Que choisir?* Sept. 1995.
7. J. Ménard, «*La santé publique: alibi ou bien partagé?*», *Bull. Ordre Pharm.* n° 369 Dec. 2000, 439.
8. Article R. 5015-48 stipulates that «*The pharmacist must perform all aspects of the dispensing of the drug, including with its issuing: 1. The pharmaceutical analysis of the prescription; 2. (etc.)*» (our stressing). For the analysis of the notion, see «*L'autonomie de l'acte pharmaceutique*» prec. 749 and following.
9. (The doctor does not “*choose*” a “*brand*”, he prescribes a substance; the pharmacist does not “*sell*” a “*product*”, he dispenses a medication).
10. See M.-H. Renault «*De la corporation d'apothicaires à l'Ordre des pharmaciens. Un monopole dénoncé, la pharmacie d'officine*» *Rev. dr. san. soc.* 1998, 737.
11. F. Megerlin, «*L'autonomie de l'acte pharmaceutique...*» op. cit.
12. “*When the interest of the patient's health seems to require it, the pharmacist must refuse to dispense a drug. If this drug is prescribed, the pharmacist must immediately notify the prescribing physician of his refusal and mention it on the prescription.*”
13. Article R. 5015-61 stipulates that “*the pharmacist may only modify a prescription with the express, prior consent of its author, except in the event of an emergency and in the patient's interest.*”
14. This is the title of section I of the chapter of the Code of professional ethics devoted to community pharmacists.
15. V. F. Megerlin, «*De la sécurité à l'expertise du soin?*», *Bull. Ordre pharm.* Oct. 1999, 465, and «*L'opinion pharmaceutique. Une révolution à l'officine*», *Rev. dr. san. soc.* 1998, 678 and following.
16. See «*L'autonomie de l'acte pharmaceutique*», prec., 755 and following; 760 and following.
17. For health reasons (complexity of therapeutics, behaviour of patient, etc.) but also technological reasons, as doctors have more and more computer prescription software.
18. See E. Schmitt and F. Locher, «*Cadre juridique du circuit du médicament en milieu hospitalier consécutif à l'arrêté du 31 mars 1999*», *Bull. Ordre Pharm.* Oct. 1999, n° 364, 427 and following. Article 6 of the decree of 31 March 1999 refers to article R. 5015-48... but then adds that “*to accomplish this dispensing, the pharmacist can ask the prescribing physician for all useful information*”.
19. See below, and our commentary of the modification of the texts during the debate on substitution, *ibid.* prec., 754.
20. Thus the affair of the prostitute and Ventoline, in *Le Moniteur des pharm. et des laboratoires*, 17 May 1997.
21. For all of these issues, «*L'autonomie de l'acte pharmaceutique*» prec., 757 and following; 764 and following.
22. See our analysis, *ibid.* prec., 754 and following.
23. In both cases, CE 29 July 1994, M. C. Req. n° 105095 and Mme G. Req. 121615. See also the «*Tableaux de posologie*» from the Pharmacopée française, 10th edition.
24. *Comp.* of decisions in the other direction in civil matters, which we criticise on this point, for example Paris 1re ch. Civ. 6 April 1990, *Bull. Ordre* 333, Apr. 1991, 147; Civ. 29 May 1979, *Doc. pharm. juris* n° 1691.
25. See article 6 of the decree of 31 March 1999 prec.; E. Schmitt and F. Locher, «*Cadre juridique du circuit du médicament en milieu hospitalier (...)*» prec.; see also the *Référentiel de pharmacie hospitalière*, SFPC 1997, 130.
26. See the nuances in this sense, with our full approval, of E. Schmitt and F. Locher, prec., 434.
27. See in particular the ordinal reflection on quality assurance carried out by Henri Lepage, vice-president of the CCA.
28. See «*L'autonomie de l'acte pharmaceutique*», *Rev. dr. san. soc.* 2000, 753.
29. On these issues, *ibid.*, 756.
30. For an overview of these issues, *ibid.* 761 and following, spec. 765.

31. See our detailed study «*L'autonomie de l'acte pharmaceutique. Vers une réforme du Code de déontologie?*» *Rev. dr. san. soc.* 2000, 746.

32. «*L'opinion pharmaceutique. Une révolution à l'officine*», *Rev. dr. san. soc.* 1998, 665; for a practical presentation, see the excerpt from the *Guide de stage à l'officine*; *Les Actualités pharmaceutiques*, n° 392, Dec. 2000, 39.