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Discourse on Safe Drug Use
Symbolic Logics and Ethical Aspects

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Abstract

Drug safety is not a matter for healthcare professionals alone. Patients are also involved, at three different levels: (i) in the behaviours patients adopt to reduce the adverse effects of the drugs; (ii) in regard to what some doctors say to their patients about drug risks; and (iii) in what the pharmaceutical industry says about self-medication and risks. This article will examine these aspects on the basis of information gathered in France during anthropological studies on drug use.

(i) Patients' concerns about reducing adverse effects give rise to a series of behaviours relating to drug use. Patients start with the identification of what they regard as a risk inherent in the substances or linked to the uncontrolled use of drugs, and try to neutralize the risk by modifying or modulating the prescriptions in line with various parameters. Dimensions as varied as the nature of the prescribed drugs, the quantity, the dosage and the preservation of certain functions or organs are taken into account, and patients follow their own rules of conduct in order to reduce risks. These dimensions bring into play characteristics of both the drug and the individual, and take into account the effects or the risks of drugs in their physical, psychic, behavioural and social aspects.

(ii) Doctors' discourse towards patients regarding the risks and possible effects of drugs is examined, in particular the discourse of those who choose to hide the undesirable effects of drugs from their patients with the aim of not jeopardizing the patient's compliance. This situation involves comparing two logics: ethics of care versus ethics of information.

(iii) Regarding the pharmaceutical industry's discourse on self-medication and risks, although on the one hand it promotes self-medication on the basis of patients' growing desire for autonomy and competency, on the other hand it discourages the use of the home medicine cabinet for reasons of safety, which questions the ability of patients to use drugs properly.

This article aims to demonstrate that the various behaviours and discourses relating to the risks of drugs are embedded with symbolic, ethical and cultural logics. As a consequence, above and beyond work carried out on the question of pharmacovigilance, examining the issue of safe drug use involves studying the human – social and cultural – aspects that govern part of the behaviours and practices relating to drug safety.

The issue of drug safety is an important one, not only for health professionals but also for patients. Indeed, if one takes into consideration the definition that Théophile and Bégaud[1] propose, which considers pharmacovigilance as "part of pharmaco-epidemiology devoted to managing

and preventing risks'', pharmacovigilance clearly comes across as an activity falling within the competency of professionals: ''pharmacovigilance covers all activities aimed at detecting, evaluating, quantifying, preventing the harmful effects of drugs, and at optimizing the benefit-risk ratio through adapted, individual or collective decisions: to prescribe a drug or not, to adapt or to interrupt a treatment, to modify the indications of the drug or the information given to doctors or patients, or even to withdraw the drug from the market'' (translated from French).[1]

However, patients are also concerned about reducing the risks of drugs, given that they manage their prescriptions in order to limit or avoid risks related to the consumption of drugs that are likely to have adverse effects, even though the logics on which they are based are not the same as those of the professionals. Whilst it is of course not in patients' power to withdraw any drugs from the market, they can nevertheless remove them from their shopping basket or choose not to fill their prescription. On the other hand, doctors do have a discourse directed towards patients about drug risks, and what they choose to say raises questions of both a medical and an ethical nature. Finally, the industry also has a discourse directed towards patients, not only through patient information leaflets, but also in the debates on drugs that take place in the public sphere, in particular on self-medication.

This article focuses on certain discourses and practices with regard to the issue of risks of pharmaceuticals regarding (i) the behaviours patients adopt to reduce the adverse effects of the drugs; (ii) what some doctors say to patients about drug risks; and (iii) what the pharmaceutical industry says about self-medication and risks. Overall, this insight will allow us to underline the symbolic logics and ethical aspects that influence these behaviours. To illustrate this, three anthropological research projects in France are discussed:[2,3] one on patients' relationships with drugs according to their religious-cultural origin, the second concerning the information passed between patients and doctors, including information relating to pharmaceuticals, and the third on self-medication.

The purpose of anthropology is the explanatory and comparative study of the social and cultural characteristics of human groups. It starts by taking an in-depth look at a small group of people and analysing their discourses and practices. It is the latter that provide the data used for qualitative analysis, which are collected through long-term observation in order to identify – through the gestures, speech and actions of individuals, along with their recurrence and meaning within a given context – what this says about their logics and systems of thinking. At the methodological level, anthropology is largely based on monographs and case studies. On the basis of the data collected, it does not pretend to provide results that are statistically representative, but aims to uncover trends that allow us to reveal both the constants and the differences between the individuals and groups under study. In this respect, Hamel[4] makes the distinction between 'statistical representativeness' and 'theoretical representativeness', echoing Mauss,[5] for whom ''it is an error to believe that the credence a scientific proposal deserves closely depends on the number of cases believed able to verify it.'' The sample is constructed using what Hamel[4] calls 'methodological imagination', where the case under study has the epistemological qualities that enable it to 'represent' the group as a whole and which allow generalization. As Bourdieu[6] said, ''a single, well-constructed case ceases to be particular.''

1. Patients' Behaviours

Patients' concern for reducing adverse effects gives rise to a series of behaviours (rules of conduct) that go from the modification of medical prescriptions to the refusal to follow them, liable to be labelled as non-compliance behaviours by medical doctors. Starting from an identification of what they regard as a risk inherent in the substances, or linked to uncontrolled use of drugs (even when they are prescribed), patients try to neutralize these risks by modifying or modulating the prescriptions in line with various parameters.

The data on which this analysis rests have been collected within the framework of a study carried

out in France on the behaviour of patients with regard to drugs.[2] The study was carried out among four groups of patients from different religious backgrounds: Catholic, Protestant, Jewish and Muslim. This qualitative study consisted of interviews and observations, both in hospital settings and in patients' homes. The aims of the study were to determine what views these subjects had of drugs in general, in particular psychotropic drugs, on what basis they did or did not use them and what stood in the way of their use. Subjects were chosen on the basis of their families' religious background and not of their belonging to an organized religion. The originality and uniqueness of the study was that it measured the 'imprint' left by culture (and family religious background is part of culture) among patients who were sometimes totally unfamiliar with any religious beliefs. The study shows that religious-cultural background influences representations about psychotropic drugs, the body and medical authorities through the espousal by individuals of the primordial values passed on in their families, a product of their cultural heritage. The research was carried out over a period of 5 years among 186 patients belonging to diverse socio-professional categories. This study does not pretend to define Protestant behaviour compared with Catholic, Jewish or Muslim behaviour, not just because the collected data have no statistical value but also because it is not possible to totally separate the cultural variable from the other variables. The study has the more modest aim of revealing trends, which can be objectivized through the observation of recurrences within the same cultural milieu, here defined as the fact of having a common religious origin, and observed among persons of diverse social milieus. In this respect, patients from equivalent socio-professional categories were compared across those four cultural groups in order to neutralize the strictly sociological variable.

Risk management techniques differ according to the patients because they are in keeping with their cultural belonging, mobilizing various cultural representations. They take into account dimensions as varied as the nature of the prescribed drugs, the preservation of certain functions or organs, and the quantity and dosage of the drugs consumed.

Patients also try to limit the use of drugs suspected of having adverse effects on a given part of their body or on a given function or capacity. In this respect, although psychotropic drugs (be they antipsychotics, antidepressants, tranquillizers or hypnotics) are reportedly consumed extensively in France[7] – an over-consumption that is largely explained by over-prescription – there is a great deal of reluctance to take them due to various types of fear: fear of physiological or psychological dependence, fear of changes in cognitive abilities, fear of a change in personality or of feeling sick.

Patients of Muslim origin express reluctance to take psychotropic drugs because of the harmful effects they suspect these substances to have on their body and on social behaviour through their deleterious effects on the heart. For instance, a teacher in electronic engineering considers that psychotropic drugs ''act negatively on the heart and mind. With such drugs, one is no longer responsible for what one does; one becomes mad,'' he says. This idea refers to a recurrent conception of the heart, which has a special quality for Muslim families, as witnessed by the people's daily behaviour. To understand why they show such specific behaviour regarding the heart, it is necessary to stress what the heart represents for Muslim families. There are many sentences in the Koran that refer to the idea that the heart is the seat of moral sense and reason, of moral and spiritual life. It is no mere coincidence that religious therapeutic objects (made of pieces of paper on which Koranic verses are written and wrapped in a piece of cloth) are frequently carried around the neck, over the heart; on one occasion, a patient even took a cardiologist's prescription, made two holes in it and slipped a string through them in order to wear it around his neck, over his heart. The importance given to the heart can also be seen when a Muslim nurse decided to choose another doctor for her child because the first one did not listen to the baby's heart, or when a Muslim store manager considers that some doctors are not conscientious because they listen to patients' hearts through their clothes.

Just as we have seen with the heart, there are a certain number of behaviours that can be explained by the desire to preserve certain functions or organs of the body, to which the drugs are suspected of posing a threat. This is the case with people from other cultural groups who also have reservations about psychotropic drugs, albeit for different reasons. What must be noted here is that the undesirable (physical, social, psychiatric and behavioural) effects of medications are not the same for everybody, despite what is explicitly stated in the patient information leaflet.

Among Protestants, the reluctance to take psychotropic drugs is often due to a fear of the dependency they create. It is interesting to note that the refusal of dependency is a core value among Protestants and that it also influences their general wish to manage their illness, their prescriptions and their treatments in a totally independent fashion.

Reluctance among Jews to take psychotropic drugs is related to fear of the loss of memory that prolonged taking of this type of medication might induce. Among Jews, whether they are believers or not, memory is a cardinal value that must not be endangered. The fact that memory is highly valued not only has something to do with the fact that religious instruction includes the obligation of memory since the destruction of the Temple, but can also be related to its links with history: remembering means protecting oneself. The history of persecutions experienced throughout the centuries, especially in the 20th century, has reinforced this injunction to remember and to be wary. The continued reference to memory recurs as a recurring theme or 'leitmotif' in Jews' expression of the fear associated with taking psychotropic drugs.

It must be stressed here that there is not always consistency between views and actual practices, in so far as patients sometimes take the drugs even when they are reluctant to do so. Yet even when they do take psychotropic drugs, many patients do not do so with a light heart, or they may try to reduce the doses of the prescribed drugs.

As we can see, all these dimensions bring into play both representations of the drug and representations of the person, and take into consideration the effects or the risks of drugs in their physical, psychic, behavioural and social aspects. But other logics can be noted, in any type of cultural group. Some choose to restrict the use of drugs to a certain number according to a logic that is not validated by doctors; patient vigilance here consists of limiting the number of pharmaceutical drugs to take in order to reduce risks of interaction, at the cost of a reinterpretation or a rearrangement of prescriptions. But this can also happen within the framework of self-medication, where patients decide to prevent the drugs they use from interacting negatively, and base their choice on a quantitative logic. For instance, one school teacher considers that the number of drugs used must be limited to three. ''As soon as one takes more than 3 drugs, there are risks of interference,'' she says. The iatrogenic risk here relates to the quantity rather than the quality of the drugs. This is why, when there are more than three drugs prescribed, she decides not to comply with the full prescription and chooses, from the list, a maximum of three that seem to her to be the most necessary.

Fear of the iatrogenic risks resulting from drug consumption causes some patients to refuse to practice self-medication, believing that the mix of drugs is dangerous, whereas on the other hand it is the need to be vigilant that leads other patients to want to acquire a medical understanding of drugs and to dream of software that might be used to see whether the drugs they wish to take are compatible.

Therefore, despite the supposedly high level of drug consumption in France, patients do not necessarily want to cumulate the drugs (i.e. to take the greatest possible number or quantity of drugs). Some patients prefer to ensure that the drugs they take suit their body and their being. Some patients have vigilance behaviours that consist of limiting the undesirable effects of drugs by trying to adapt them to their self, according to logics that, once again, are not necessarily those of their doctors. This leads to a redefinition of dosages, which implies the recognition of a relationship between the drug and what the person is – fat or thin, strong or fragile, old or young, man or woman, etc. – leading patients to either

increase or reduce the prescribed doses of drugs, with dose reduction generally being motivated by the wish to reduce the harmful effects of drugs.

2. Doctors' Discourses

Whilst patients are very keen to avoid the side effects and risks of drugs, it is not rare for doctors to attempt to hide them. This leads us to consider doctors' discourses within the framework of the doctor-patient relationship (and therefore, in concrete terms, of the consultation) concerning the risks related to certain drugs and the place given to the contents of the patient information leaflet provided by the pharmaceutical company, both in hospitals and in private consultations. On this point, the data collected come partly from the study described earlier,[2] within the framework of private consultations for all types of pathology, and partly from another study carried out on the issue of information exchanged between doctors and patients in hospital departments (oncology and internal medicine).[3,8] It covered 80 patients (60 with cancer and 20 with other pathologies, including chronic inflammatory illnesses or autoimmune illnesses) of different ages (between 30 and 80 years of age), of both sexes and from various socio-professional backgrounds. With the aim of the research being to highlight the logics and mechanisms at the root of information exchanges between doctors and patients, the investigation consisted of observing medical consultations and then separately meeting the doctors and the patients in order to see how the verbal exchanges were constructed, and to decode the reasons and mechanisms of their acts and words.

Despite the Law on Patients' Rights of 4 March 2002[9] guaranteeing patient information, the observation of consultations shows that not only do medical doctors not provide full and complete information on the risks of a treatment, but that they sometimes choose to conceal the possible effects of drugs from patients, or even to deceive patients about these effects so that there is no risk of this information discouraging them from taking the prescribed drug or causing them not to comply with the prescribed treatment. Adopting an ironic stance in relation to the 'shared decision' model, one doctor takes umbrage at the legal obligation to tell a patient about the risks of the treatment: ''Why upset the patient when he might in any case die of renal or cardiac insufficiency if I do not give him the treatment? The shared decision system means shared anguish! We no longer have the right to prescribe cancerous drugs without telling patients, yet the risk is theoretical!'' Another doctor explains: ''With certain treatments there are risks for the kidneys; so I sometimes hide the side effects of the drugs – for example, methotrexate can cause pulmonary fibrosis and with endoxan there's a problem after 30 years: there is a risk of leukaemia. There's no point telling them, or else they won't take the treatment!''

Regarding treatments and their possible effects, we also observed forms of withholding information through the attitude of some doctors who discouraged patients from reading the patient information leaflet provided by the pharmaceutical company, with the objective of encouraging compliance. ''You read too much'' was one doctor's reproach to a patient who was worried about the adverse effects mentioned in a drug's patient information leaflet provided by the pharmaceutical company, and about the quantity that he had been prescribed, which was greater than the dosage recommended in the patient information leaflet. They tend not only to keep quiet about unpleasant side effects so that such information does not discourage patients from taking the drugs and to ensure that they will be compliant, but sometimes even deny the information contained in the instructions. Indeed, some go so far as to assert that the content of patient information leaflet about possible effects is false, in order for the patients to submit to the prescription. What doctors choose to say to their patients about drugs varies widely, depending on the nature of the disorder being treated, but the dissimulation of the risks of certain drugs is found just as much in cases of benign pathologies as in serious pathologies. The practice thus consists of not being completely transparent with the patient, in the patient's interest, within the framework of a doctor-patient relationship that remains paternalistic.

In this article we approach the issue of the ethics of information. Our objective is not to comment on the ethical nature of the behaviours that are examined here – the ethical aspect of the issue of information and truth is very widely discussed in existing literature.[10,11] On the other hand, it is important to stress the place taken by ethics in doctors' justifications for their practices, since some doctors choose to hide the effects of drugs from the patients – or even to lie to them on this subject – in order to not alarm them and with the aim of not jeopardizing their compliance, referring to what they consider to be ethical professional behaviour. This situation leads to confrontation between the two logics (ethics of care vs ethics of information) that they say they follow. Doctors justify such an attitude in the name of the necessity of patient compliance, which constitutes a kind of paradox, both logical and ethical, since it is in the name of compliance (identified as being in the patient's interest) that doctors adopt a behaviour which is contrary to patient information on drugs and their possible effects.

3. The Industry's Discourse

Another social actor must also be taken into consideration in this context – the pharmaceutical industry. Directly related to the issue of safety, it must be noted that the scandals which arose around drugs such as Vioxx® (rofecoxib) resulted in patients mistrusting the industry's discourse. Just as patients have learnt to mistrust doctors because they know them to often dissimulate facts, some patients are distrustful of the pharmaceutical industry when they know that risks have been hidden. They want to be 'enlightened' in accordance with the modern notion of 'patients' rights', and think that they should be clearly informed of any drug-related risks, especially when they need to resort to self-medication.

But now we come to what interests us most – the pharmaceutical industry's discourse regarding self-medication in relation to the issue of safety. The pharmaceutical industry (in France represented in particular by AFIPA ['Association Française de l'Industrie Pharmaceutique pour une Automédication responsable', which translates as French Association for the pharmaceutical industry for responsible self-medication] and LEEM [Les Entreprises du Médicament, i.e. the pharmaceutical companies]) support the development of self-medication, which they define as 'the spontaneous non-prescribed purchase of drugs at a pharmacy'.[12] Moreover, the industry is generally in favour of free access to drugs (that is to say, over-the-counter drugs). However, just like the authorities, the industry defends the monopoly of pharmacists on the distribution of drugs, and advocates 'encouraging doctors to assist in the promotion of self-medication', in order to 'allow them to supervise their patients' drug consumption'.

Beyond the economic motives that are obviously at stake here, the industry is also attempting to take a stance at a human and philosophical level by declaring that it is necessary to encourage 'responsible self-medication' in order 'to satisfy people's increasing desire to take care of themselves and to be responsible for their health',[13] echoing the view of the Ministry of Health who declared, when promoting self-medication, that it is willing to ''accompany patients in their will to be the actors of their health''(translated form French).[14]

Analysis of the industry's discourses in this debate shows the extent to which it differs from the point of view of doctors, who are often opposed to self-medication, precisely because of the risks involved. The situation is one in which the pharmaceutical industry presents itself as the defender of users, affirmed in their autonomy, making the patients 'responsible' individuals, asserting their rights and their competences. However, there is one flaw in their discourse which shows that they do not have complete confidence in the ability of patients to be vigilant with regard to drugs. We can clearly understand that, commercially speaking, it is desirable that patients buy drugs and preferably seek the advice of the pharmacist rather than taking what they think they need from the medicine cabinet at home. Yet whilst we might accept that the consumption of drugs without checking with the pharmacist may involve certain risks, the negative view of the

family medicine cabinet testifies to the wish that patients stop using it, even though the medicine cabinet may contain what is appropriate for their problem. The patient's competence and aptitude for vigilance is called into question here. Just like public policies, the industry is sending patients a somewhat contradictory message, recognizing their competence regarding vigilance towards drugs, whilst at the same time denying any such competence.

4. Concluding Remarks

The anthropological perspective does not seek to impose a normative judgement on the phenomena it studies. But the analyses of behaviours and discourses of the social actors (health professionals, patients and industry) show how all involved have strategies aiming at an optimal use of drugs; all are involved, in their own way, in managing safety and efficacy, although those strategies are closely aligned with symbolic, ethical or cultural logics.

The way in which a society manages the issue of drug safety does not depend solely on pharmacovigilance data, but also on symbolic logics and cultural representations, even if these are outside more traditional medical rationality.

An examination of the question of safe drug use and safety thus means studying the human – social and cultural – aspects that govern some of the attitudes and practices relating to drug safety. On the basis of the three examples set out here, the analysis of the attitudes and practices of the different actors (patients, doctors, industry) regarding safe drug use by patients illustrates just how much they can be underpinned by ideological, moral, social and symbolic aspects.

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