Volume 1 • Issue 2 • 2017

Research Article
Oral Health and Dentistry
ISSN: 2573-4989

Drugs in Dentistry: Medicolegal Responsibilities and Problems

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Received: January 17, 2017; **Published:** March, 11, 2017

Abstract

Objectives: The aim of this study is to examine drug prescription in dental practice, with particular attention to the relevant law provisions.

Materials and Methods: The various aspects of the subject are analyzed, both from a clinical point of view and from a medicolegal one, without neglecting normative standards nor the obligations held by each and every healthcare professional in their dual capacity of prescriber and attending doctor.

Results and Conclusions: This publication discussing the need for dentists to possess an adequate knowledge of drugs and medical substances, of their correct use and of their desirable or undesirable effects, is the result of a determination to make the professional category fully aware of their responsibilities in this field. Accountability involves appropriateness of use and adequate examination/evaluation of those substances, as well as suitable forecasting/management of their effects together with identification of areas of variability and of all the unavoidable clinical and medicolegal repercussions. The more one knows about drugs and legislative provisions, the fewer pertinent clinical and medicolegal problems will arise. Moreover, this will result in a higher therapeutic effectiveness.

Keywords: *Drug; Adverse Drug Reaction (ADR); Adverse Event (AE); Complication/error; Forensic medicine*

Volume 1 Issue 2 March 2017

Introduction

Drugs are a very powerful "health instrument" and can considerably improve the quality of life. The present-day extension of the average life expectancy is also due to a higher and more focused availability of medical substances [1-9]. However, each medicine may have negative or undesired effects. The "undesired" effects are physiologically part of the action of the medical substance and of the drug, but they can disturb both the patient and the prescriber.

By the term "drug" we mean any "substance that may be used with a diagnostic, therapeutic or preventive aim". In Italy drug is the active ingredient. Medication is the drug that has been transmitted by its specific excipients, in its specific formulations, accompanied by its technical leaflet and approved by the Italian Agency for Drugs (AIFA), then sold, prescribed and administered. The same drug can be a component of different medications.

Drugs (10) are "goods that influence or may influence the health and the wellness of the consumer". This implies great responsibility not only for the producers but also for the end users, whether they are the attending doctor or the prescriber (in case the two differ).

As a result many problems can be avoided if drugs and legislative regulations are better known [1-10].

1. Bachelor's degree in Dentistry and Drugs

In Italy the law regulating the dentistry profession, DL 409/1985, particularly at article 2, declares that dentists can prescribe all the medicines that are necessary to the practice of their profession. This is apparently a logical and easily interpreted prerequisite.

The prescription and the administration of some classes of drugs that are commonly necessary in the dentistry profession–such as the analgesic/anti-inflammatory, the local anaesthetics, the antibiotics that act on the pathogen flora of the oral cavity–may be viewed as obvious and taken for granted. Less logical and justified may appear to be the prescription of drugs for the therapy of non-dental diseases. Sometimes, however, these drugs are necessary for the practice of the dentistry profession (for example: prescription of a benzodiazepine when in the presence of agitation or anxiety during the phase of pre- and post-intervention or in patients with particular handicaps).

All the more reason, then, to use emergency drugs in all those conditions or situations that can lead to serious damage or to an imminent danger for the patient's life (e.g. to use cortisone medicines in case of allergic reactions or use an anti-hypertensive drug in case of a hypertensive crisis). The resolution AIFA of May 29th, 2012 (GU no. 143 of June 21st, 2012, ref. Title IV Legislative Decree 219/2006, articles 93-94) and the clarifications by the Health Ministry and by the National Federation of the Association of Surgeons and Dentists authorise dentists to prescribe and use medicines based on atropine sulphate. On the other hand, if the Italian legislation had not allowed dentists to prescribe, use and administer this kind of drugs, that would have created situations potentially putting at risk two important basic rights protected by the Italian Constitution: individual health and life.

The problem is of a different nature: it involves not the possibility of administering and prescribing certain drugs, but the competence of those who administer and/or prescribe them.

There is a great deal of controversy around this matter, and the positions taken by forensic scientists and experts show widely diverging views. Therefore it is appropriate and useful for the dentist (the doctor who practises dentistry) to adequately provide documentary evidence for the events in question, as well as exhibit the achievement of a specific and demonstrated expertise (educational practice, BLS and BLSD courses, clinical experiences and/or ward practice, etc.).

Independently of the type of degree obtained, using, administering and prescribing drugs or medical substances expose dentists to precise responsibilities, both clinical and medicolegal. All these activities involve a deep knowledge, not only about the product used and its effects, but also regarding the patient's clinical condition and the possible interferences and collateral effects. Not making use of a product or using it in the wrong way when missing precautionary and evaluative procedures that are correct and validated may lead to unintentional behaviour, even more if damage has been caused and the behavior not only violates the law, but also infringes professional ethics and moral obligations of each doctor.

However it is not possible [1-11] to exclude the risk of damaging a person by means of the administration of drugs, even if this takes place according to a correct balancing between possible negative effects and hoped-for advantages (probabilistic calculation). In this case malice or fault ("not guilty damage", i.e. not consequent to a professional mistake, namely "complication") would be excluded. Anyway, an obligation exists for the doctor to be able to manage the complication. You cannot forecast when the adverse event will take place; however, when important benefits are in sight, a correct evaluation of the elements of exposure to the risk can help reduce the possibility of it happening (the concept of "acceptable" risk).

As the matter is so important, each medical professional must keep constantly up to date, in terms of knowledge and analysis, on the most recent scientific acquisitions and clinical evidence. Furthermore, these elements are widely made known among healthcare professionals by the drugs-surveillance service. This kind of service not only follows a very strict procedure of tests and premarketing validations [1-10], but it intervenes during the phases following all those adverse or undesired events that are reported by healthcare professionals. This reporting is compulsory and regulated by specific laws, but it is also a matter of professional ethics and a moral duty [12,13].

In practising the dentist's profession it is fundamental to have a deep knowledge of those drugs and medications that are not strictly related to dentistry. This is very important in order to avoid negative or fatal interferences due either to other substances prescribed to the patient by other doctors or to diseases or conditions that are not strictly connected to dentistry.

2. Adverse Events and Negative Reactions to Drugs

Even an appropriate use of drugs or medical substances can lead to unknown reactions, to undesired and involuntary responses (abnormal type A reactions, predictable, dose dependent; type B odd reactions, unpredictable and non-dose dependent, frequent with predisposed subjects) [13-16]. Spontaneous reporting of adverse reactions must not be considered as a simple bureaucratic obligation; actually, it constitutes a fundamental, easy and economic instrument–scientifically and culturally valuable-for identifying those alert signals pertaining to the toxicity of medications that are not recognized or recognizable during the pre-registration study (M. Magnani, Letter Prot. 262 of March 23rd, 2004, by the person in charge of Drugs Surveillance with the AUSL of Bologna).

The acronym AE (from the English expression "Adverse Event") stands for "adverse event" [17-18]. We can observe an adverse event during a medical operation independently of the existence of a causality link with the operation itself. An adverse reaction (or ADR, from the English "Adverse Drug Reaction") is, instead, any noxious or non-intentional reaction to a medication that has been administered for precautionary, diagnostic or therapeutic purposes [17]. We suppose that there is a causality link between drug and event. In 2012 this concept expanded so much that it came to include harmful and undesired effects due both to a medication used in accordance with the indications as per the commerce introduction authorization, and to the exposure to such medications for professional reasons [9-15, 19-20].

AE and ADR do not constitute medical mistakes, unless previous recognition and highlighting of the problem are known (Bollettino di Informazione sui Farmaci, or BIF-Drug Information Bulletin, containing notes sent by the drugs-surveillance service as well as other sources of specific updated information).

In Italy it is possible to send reports to the AIFA (ref. Ministerial Circular of September 24th, 1997 that implements the Legislative Decree of February 18th, 1997 and No. 219 of 2006) [13] by filling in the appropriate "electronic form" that is available on line (Public Healthcare Agencies or link of the Health Ministry) [19,21].

3. Some Historical Data

The benefits associated with the administration of medical substances or of substances viewed as curative have been known since ancient times, as well as their possible inefficacy or even noxious effects. Nevertheless, only in 1960 the US Food and Drug Administration promoted the ADR register, and the first intra-hospital programs of drugs-surveillance (Johns Hopkins and Boston) started. In Italy the Legislative Decree of February 18th, 1997, established the National System of Drugs-Surveillance, which works with the European Medicines Agency (EMA, ex EMEA) through a department of the Health Ministry.

In 1963 the International Committee for the Safety of Drugs considered it worthwhile to monitor the safety of substances on the market and develop strategies to reduce the risks and increase the benefits connected to their use, also through the spreading of information on a large scale [13].

4. The boundary Between Clinical Practice and Experimental Use of Medicines

Drugs and substances cannot and must not be used if their use and launch on the market are not authorized. Only a few experimental clinical projects are allowed, and they are monitored in accordance with the current regulations (Ministerial Decree of July 15th, 1997). In Italy this experimentation is regulated by very strict norms that safeguard and protect people voluntarily accepting to undergo a specific programme.

There also exist so-called "off-label" medicines. These substances are used with different aims and dosage or on different kinds of populations than those usually known (they are used not in accordance with the authorizations given by the Ministry of Health or with the terms specified in the list issued by the Single Commission for Drugs). In these cases the suggested dosage is not respected, and the contraindications listed in the Summary of Product Characteristics (RCP) are not considered [10-14]. It is not a matter of a systematic use of these medicines. It is an occasional use of substances about which there is clear information of efficacy and usefulness (scientific proofs, guidelines). Those substances are launched on the market with different clinical indications. Their use cannot leave out the existence of such facts, as well as correct and precise information given to the patient, followed by their consent.

The prescription and the use of such medicines amplifies the civil and penal responsibility and the duties of the doctor (anamnesis, diagnosis, prescription/administration and monitoring).

A typical example, in dentistry, is the use of metronidazole in paradontology for infections supported by anaerobic bacteria that cannot be otherwise controlled. The Italian National Health Service (SSN) distributes that medicine only to female subjects, and only as regards other therapeutic indications.

5. The act of Prescribing

Prescribing medicines is a legally relevant medical act ("complex act") [20, 22-28] both from a clinical, administrative and economic point of view (as for the drugs to be paid by the SSN), and from a documentary one. The Court of Cassation declared, with sentence No. 13315 of March 31st, 2011, that a doctor accomplishes a complex activity by giving a prescription, which acquires a status of certificate [27]. The act of prescribing implies diagnostic evaluations carefully arrived at [28,29]. This act results in a therapeutic prescription filled in and signed by a doctor or a dentist by hand or by means of an electronic device. The prescription must be written in an indelible, clear and legible way, possibly without corrections. The corrections, when present, should be countersigned. The prescription "contains dietetic suggestions and directions about therapies with the pertaining dosage and instructions for use" [23]. This document involves taking on an important responsibility on more than one level: professional, disciplinary-deontological, conventional, civil and penal. This is true for both the prescriber (doctor or dentist) and the pharmacist (the person who provides the drugs).

The medical prescription has the essential function of reducing the risk connected to the use of drugs for health safeguard [27]. It is also a tool for controlling the public spending whenever the drugs are to be paid by the National Health Service (SSN) [10-27]. It is a written document with its own formal requisites [20], through which it is possible to prescribe drugs that are recognized as effective and useful, in accordance with the ministerial and State dispositions. On the prescription there are compulsory details, such as identification data of the prescribing doctor, name and surname of the patient (mandatory where it is required by rules, but preferable when not compulsory), name of the medicine or of the active ingredient (with the direction "not replaceable", if valid and justified premises exist), place and date of the compilation and signature of the doctor/dentist. The directions regarding the pharmaceutical form, the formulation and the dosage of the substance are not compulsory on the prescription. But it is highly advisable to give them, and it is also a sign of accuracy. In the absence of specific directions, the pharmacist has to provide the medicine at the lower dosage. It is highly recommended to clearly indicate any reference to pediatric or adult formulation in order to avoid any situation that can cause negative events.

Without any specification about "non-replaceability" of the prescribed medicine, the pharmacist, according to the current rules, is authorized to provide an equivalent or generic medication. The responsibility for a possible negative reaction in respect of this substitution, however, falls back into the person writing the prescription. This means that if the doctor has a justified reason or if he knows something about the possibility of negative or adverse reactions (for example allergies to excipients), he would be obliged to point out the non-replaceability of the product.

On the contrary the sentence of the Court of Cassation No. 7529 of May 29th, 2012, confirmed that there is no responsibility for the doctor in case the patient does not observe the medical prescriptions (there was a case of death of an old patient who did not have the force or the will to take the prescribed medicines, with a consequent progressive weakening of the breathing capacity) [30].

6. Professional Updating and Relevant Rules

Professionals in the healthcare field have the duty to keep themselves up-to-date with respect to the recent medical-scientific discoveries (Legislative Decree No. 502 of December 30th, 1992 and in particular the articles No. 16 bis and 16 ter). This is true for drugs prescription as well. In case of a proven damage caused by a mistaken conduct, the doctor will have to demonstrate the non-involvement of his own behaviour for each causal hypothesis of offense. Moreover he will be responsible for personal harm or for unintentional homicide in case of death.

As far as legislation is concerned, ample space is given to the doctor's decisions regarding preferences, choices and methods of administration/application of medicines. But this autonomy and self-determination are limited by precise national and community regulations, by the specific authorizations of the products, the guidelines, the recommendations and the rules regulating clinical experimentation.

No drugs can be sold, bought and administered/prescribed if their usage or their launch on the market are not specifically authorized by the State. If that were to happen, a serious fault would be debited to the doctor in case of damage or complication.

Obviously the case of lack of results and positive outcome in view of correct diagnostic and therapeutic evaluations is different.

The use of a medication has to comply with correct and validated directions, dosage and method of administration, things that the doctor has the precise duty to know (it is suggested to carefully read the technical sheet of the medicine, in particular with reference to section 4.3) [10-16, 18,30,31].

7. The Choice of The Medicine

"The choice of a toxic medicine without carefully evaluating and comparing its positive effects in respect of the possible negative serious ones, certainly constitutes a medical fault, since such a medicine has to be administered only in particular cases and upon examination of the patient's condition, examination to be repeated during the therapy (this leads to a double connotation: culpable for the mistaken choice of the medicine, even worse in case of omitted monitoring of the negative effects)" (Penal Cassation Section IV, sentence No. 17499 of April 30th, 2008 regarding the death of a woman with a neoplastic illness who died because of a fulminant hepatitis caused by a medicine).

8. The consent

In regard to the administration, prescription and/or usage of drugs and medical substances as well, adequately informing patients and obtaining a valid consent from them constitute a legal obligation. This obviously interferes with the relationship between doctor and patient. Rarely do problems arise regarding this problem when healthy and positive effects are seen. On the contrary, in case of undesired events or of specific damage connected to the substance used, we wonder whether the patient was exhaustively informed about the characteristics of the medicine, about the possibility of undesired effects, etc. Moreover, if the patient had well understood the implications, we wonder whether he had accepted the risk on the base of what the doctor had told or promised him.

The patient has not only to be informed about the possible undesired effects of the medicine, but also about the influence of certain behaviours on the percentage of these effects and on their seriousness (a typical example is the hyperplastic gingivitis due to Diphenylhydantoin). The problem reflects very delicate aspects in the case of administration of drugs for serious and weakening diseases. A typical problem–and a current one–is that of the osteonecrosis of the jaw bones, or of the atypical fractures of the femur [32-36] or of the appearance of gastric carcinoma [37,38] following the administration of Biphosphonates in the case of diseases associated with osteoporosis or neoplastic illness [33-39].

There are practical, clinical, administrative and medico-legal problems, for dentists, related to therapeutic choices, to prophylactic intervention and to the correct management of any possible complication. In case of the appearance of a complication/undesired effect (damage), the possible fault of consent or of validated prophylactic procedures, as well as the lacking acknowledgement or the mistaken management of the complication could lead to recognize a serious fault due to carelessness and lack of diligence and skill.

In the same way the conduct of the producer is indictable, if he does not highlight the well-known possibility of the negative event on the patient's package insert or on the technical sheet [32-42].

9. Anamnesis Acquisitions

The association of social promotion Diritto e Salute (Law and Health) reports that "*the prescription of a medicine must be preceded and accompanied by adequate verification and prudence, as the omission of these elements amounts to a responsibility for fault of the doctor, both from the point of view of negligence and carelessness and as regards the lack of skill*" (Penal Cassation Section IV, sentence No. 34200 of September 12th, 2007). Practically, a correct and documented anamnesis collection and the execution of tests, specific verifications in case of doubts, problems and possible complications, are necessary [42,43].

A correct and thorough anamnesis must be acquired.

From a juridical point of view a professional is in the right if he or she refuses to administrate or prescribe a medicine for which the medical prescription is compulsory, upon request of a patient, without having any knowledge of the subject–clinical or anamnestic. Drugs constitute a source of responsibility also in the activity of dentists, both for the prescriber and for the person who cannot ignore such prescriptions [44]. The fact of ignoring the taking or not of pharmacological substances, or the existence of other pathological conditions, constitute a significant element for the acknowledgement of professional fault, in case a careless administration of other drugs or medical substances or certain therapies interferes and generates negative effects.

The absence and/or the acquisition of wrong or incomplete anamnestic data are important elements for censure and for responsibility. They cannot simply be justified claiming "*he did not ask me/he did not say that*". The same is also true when "natural", "homeopathic" substances or even "food" come into play. Patients often self-prescribe drugs or substances based on personal evaluations or free interpretations of general notions or advice of friends and acquaintances. Homeopathy cannot either be left out of the "medical professions" or be ignored by the so-called "official medicine" [44].

10. The Risks Connected To Biological Elements

The consumption of acid tartrate Zolpidem (a sleeping pill) in association with chamomile tea produces hallucinogenic effects. Also the "banal" ingestion of grapefruit juice in a quantity exceeding 200 ml/day, interferes with some medicines by augmenting their plasma concentration or boosting their bioavailability, their activity or their collateral effects [10-16, 43]. Consequently on one hand there is a contraindication to the contemporaneous ingestion of both substances (technically wrong behaviour) and on the other hand the patient has not been given an adequate piece of information.

The increasing proliferation of the so-called natural drugs and in particular the products sold in the herbalist's shops, constitute a real problem. Doctors and dentists often do not ask patients if they take them, and patients do not tell the professional if they ingest them. The idea that "natural products", "herbs" and "food supplements" (a wide category of products) by definition are good for you and that they do not hurt or create problems is extremely dangerous [10-16]. That what is natural cannot hurt is a false conviction. On the contrary there is a large number of undesired effects that relate to the "plant", to the "substance", to the product and to the patient [13]. It should be unnecessary to remember that a lot of substances of natural origin are powerful poisons. The "simple" chamomile can cause addiction or even paradox-effects.

The centuries-old use of herbs and derivatives more or less purified and mixed up cannot be a synonym of efficacy and safety in itself. It does not have the characteristics of a simple placebo. It can seriously lead to the risk of interaction with other medicines or phytotherapeutic products [13]. Some adverse reactions can also develop because of contaminations, in particular of toxic substances or phyto-complexes related to the production cycle and the harvest of the "plant", to the use of manures or fertilizers in the phases of production and cultivation (a typical example is latex), to the level of pureness of the active ingredient, etc. [13]. Moreover we can never exclude some important aspects, such as the risk of sophistications, of variability of titration of the active ingredient or the absence of adequate and proper controls during the production process, the storage and the sale of the product (this is not the case with medicines: since they are "synthetic drugs", there is a higher attention to the relevant legislation).

Products sold in herbalist's shops are not subject to the evaluation of the scientific facts or to the approval by regulatory organisms such as FDA, EMA or other national organizations [13]. In any case there is a large series of decrees and rules regulating their production, packaging, composition, labelling, advertising, etc. Actually in Italy such normative references are not so compulsory for these products, compared to the monitoring activity carried out on drugs [13].

The rules that regulate labelling prevent anyone from ascribing therapeutic properties, preventative capacities or ability to heal human diseases to food supplements. Likewise, the information on the label is usually insufficient, incomplete or non-existent. Typical is the missing reference to the "technical sheet", considering that many products are de facto commercialized in herbalist's shops and even at the supermarket (nowadays ginkgo and ginseng are very popular).

Problems related to the ingestion of these substances are particularly delicate in pregnancy and in early childhood, due to the possibility of the so-called "undesired" effects and of interaction with food or medicines [1-4, 13]. Many of these products are used by expectant mothers (who are convinced that they do not hurt the foetus or that they are less detrimental than the synthetic drugs) in order to reduce the sensation of nausea, constipation or insomnia, as well as backache or urinary tract infections. These products are able to pass through the placental barrier and/or to increase the uterine contractility [4,13]. For example the propolis and the Pyrrolizidinalkaloids (that are present in *Orchidiaceae, Boraginaceae, Asteraceae and Fabaceae*) are contraindicated for pregnant women, have a chronic toxicity (e.g. a daily ingestion of honey or contaminated milk) and they are mutagens. [10-13]. Alkaloids are also hepato-toxic and they can cause some forms of cirrhosis [13].

It is appropriate to remember that among natural products of more common usage there are: the devil's claw (*Harpagophytum procumbens*), that irritates the gastric mucosa and causes nausea; the hypericum or herb of Saint John (*Hypericum perforatum*), that is very often used for the treatment of depression and causes photosensitization, nausea, vomit, rash, asthenia and restlessness, with effects on cerebral neurotransmitters; the ephedra (*Ephedra spp*.), that induces hypertension and is nephrotoxic [13]. There are several documented cases of anaphylactic reactions to "royal jelly" or of hyperthyroidism caused by the ingestion of sea herbs and/or hepatotoxicity and carcinogenicity of other natural products [13,14,17,18,27,31,32,43]. It must be observed that the oral administration (by means of drops or pills) of fluorine–an oligo-element used for ages with success for preventing dental decay–has been the object of definite directions nationally [45,46] and internationally (Environment Protection Authority, EPA). We know there is a concrete risk of overdosage, all the more so considering the mutated habits of the subjects to be treated (chewing gum, having drinks enriched with fluorine, etc.) [45].

The sedative sweet clover (*Melilotus officinalis*), the mother tincture of garlic (*Allium sativum*) and the gingko (Gingko biloba) act on platelet coagulation and/or aggregation. Therefore they must not be used by subjects who have problems with coagulation or in association with acetylsalicylic acid, warfarin, insulin or ticlopidine [13]. Their ingestion has a great applicability also in the dentistry field. Recently a dentist has been charged with the appearance of retrobulbar bleeding consequent to a tooth extraction in an old patient who was taking gingko without telling it to her dentist. The consumption of foods rich in vitamin K (for example fish, basil, sage, parsley, spinach and beet) should be limited in case of ingestion of anticoagulants. The same is true for dairy products when there is a consumption of antifungals (as they increase the absorption of the medicine). Drinking diuretic teas with the aim to lose weight can generate electrolytic disorders.

Ginseng (*Panax ginseng*) and Guarana (*Paullinia cupana*) have an effect antagonistic to the action of some anxiolytics [13]. Some natural products are known to be able to reduce a few collateral effects of the synthetic drugs by modifying their bioavailability, absorption, distribution and elimination [13]. The liquorice, eaten by people trying to stop smoking, has hypertensive effects and it is known to cause unpleasant spots on teeth [13].

All these effects and aspects cannot and must not be ignored by the doctor [10,13,14,16-18].

The majority of scientific literature refers to studies on pharmacokinetics and pharmacodynamics carried out on synthetic products, which seldom give answers to the questions regarding "natural products" [13]. The chapter regarding the interactions between drugs is one of the most complex sectors of pharmacology and medicine. Moreover this particular field is continuously developing. It is related to the increasing amount of substances launched and to the inevitable appearance of "new interactions", which do not necessarily bring about negative effects [13,14, 16-18]. Anyway no practical problems, while administrating these substances, can be excluded [13,14, 16-18].

The growing recourse to alternative medicine and to herbal products complicates the scenario in relation to the lack of information and knowledge in the field of interactions with the traditional medicines [10,13,14, 16-18]. Therefore it is essential to get as much information as possible regarding the substances ingested by patients and, if necessary, consult the homoeopath prescriber and/or read up as far as possible about these substances. Such activity should be written down on the medical records and/or the clinical diary, and if necessary or useful, in association with a signature of the patient in order to attest the sharing of the consequent therapeutic choices. Such sharing of purposes must not authorize an unexperienced, imprudent or non-diligent behaviour, or justify mistakes, diminish the responsibility of professionals, or allow one to avoid acquiring or searching for the appropriate specific information.

11. Responsibility in The Choice of Medicines

In evaluating the medical and/or dental fault, some obligations are only apparently accessory, such as the specific, absolute indications about the appropriateness of treatment, the monitoring activity during the therapy, the management of any adverse event, the information given to the patient and his consent.

Para-physiological conditions such as pregnancy, childhood or old age and the presence of a specific pathological state, need to be carefully evaluated regarding the therapeutic prescriptions and the administration of medicines. These are frequently related to the knowledge/consultation of the scientific-clinical evidence (AIFA directions). The omission of the pertaining notes on the medical record or on the clinical diary of the patient would be particularly serious.

12. The Power To Choose

The national report on the use of drugs in Italy–which is written out every year by the Ministry of Health and Social Politics, as well as by the corresponding provincial and regional departments -- provides doctors with useful informative instruments that help to improve the pertinence of use of drugs and to identify the areas of variability by elaborating specific indicators. Such indicators often

have a strictly economic and political value (control of the public expenditure), but they promote a greater appropriateness in the usage of medicines. Nevertheless the discretional power about the choice of therapy is owned by the doctor or the dentist only. Pharmacists can check the formal correctness of any prescriptions, but they cannot give advice about the medicine, the timing, the methods and the quantities of administration. If the prescription turns out to be formally defective, they must refuse to sell or provide the medicine, unless there is an unquestionable identification of the pharmacological substance, of the indications and the methods of administration. An illegible or not so clearly written prescription would be particularly dangerous.

Finally a cause of responsibility could be the conservation and/or, even worse, the use of "rotten", "expired" or technically "defective" medicines, even when they are not toxic or dangerous, but simply totally or partially ineffective. The article No. 443 c.p. establishes a presumption of danger *iuris et de iure.*

Conclusions

The ethical duty, the code of professional conduct and the regulations (DL No. 502 of December 30th, 1992, articles 16 bis and 16 ter) require professionals to keep themselves up-to-date regarding the new medical-scientific acquisitions and evidence. This, together with a careful, prudent and scrupulous clinical-diagnostic activity, reduces the risk of undesired effects and adverse events while prescribing and administrating drugs as well.

The more doctors know about medicines, medical devices and law regulations, the fewer the problems connected with the medical-dental responsibility, the better the efficacy of clinical treatments and medications.

The adequacy of a pharmacological prescription, associated with an appropriate examination of the patient's clinical state, leads us to conclude that it will be possible to face much less clinical and medico-legal problems the more doctors know about medicines and the laws regulating their use. Moreover, their efficacy will be increased.

The authors declare that no conflict of interest exists.

Financing For the Study

The authors declare that no financing has been given to them for the present study.

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