INFORMATION ON MEDICINES:
Direct-To-Patient or Direct-To-Citizen?

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The ban on the prohibition of Direct-to-Consumer Advertising (DTCA) of prescription medicines has been maintained in the EU, but the possibility of allowing Direct-to-Patient Information (DTPI) is being studied.

The proposal that we are making at the European Pharmaceutical Law Group in response to the public consultation "Legal Proposal on Information to Patients", coincides only in part with the aforementioned concept of Direct-to-Patient Information.

Our proposal is for Direct-to-Citizen Information (DTCzI)[1], which, on the one hand, coincides with the Commission's Proposal, insofar as we also strongly believe that "information" should be provided on prescription medicines, and not "advertising".[2] This is of greater importance than it may seem, as it entails removing the concept of the "consumer" and the legal provisions governing such concept in future legislation on the provision of health and medicinal information to the population, a stance that we have defended for a long time.

However, on the other hand, our approach differs from the concept of Direct-to-Patient Information, as it does not focus so much on the idea of the "patient", but on the concept of the "citizen", since we view that it is the latter that should be the real focal point of the health systems of developed countries, for various reasons:

a) Prevention is a clear objective of current health and economic systems.
b) Respect for the free will of the sick individual must be one of the pillars of our health systems, but also the free will of the healthy individual.
c) Information on medicines not only concerns patients, but also those persons that are still not patients, having a future impact on them. The reach of such information is even greater in the case of medicines for which advertising to the public is allowed.

In any event, we should clearly stress that the choice of one of these three methods - Direct-To-Consumer Advertising (DTCA), Direct-To-Patient Information (DTPI) or Direct-to-Citizen Information (DTCzI) -, is not an issue of terminology or acronyms, but rather a case of three contrasting perspectives with different legal implications.

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[1] Amarilla, Manuel, La Información Terapéutica Directa al Ciudadano (ITDC), Eupharlaw, 2004.

[2] In those countries where this is allowed (the USA and New Zealand), a move is starting to be made away from advertising owing to its catastrophic consequences for the health of citizens. Some sectors are therefore already calling for a prohibition. It is a proven fact that the advertising of prescription drugs does not allow for the dissemination of appropriate information, increases health and pharmaceutical expenditure (jeopardizing the sustainability of its system of financing), distorts the doctor-patient relationship, poses a risk to the safety of patients, encourages the unnecessary medication of a healthy population, and undermines the citizen's right to exercise their free will, due to misleading advertising regarding the possible therapeutic benefits of the drug and the playing down of the risks involved.

I) THE THEORETICAL SITUATION

Some years back I defined Therapeutic Information (information on medicines) as "*the information produced by the pharmaceutical industry, under the supervision of the Health Authorities, and used by the doctor by means of the prescription, and by the pharmacist, together with the provision of suitable advice, within the scope of treatment with medicines*".

It may be inferred, on the basis of this definition, that it is the pharmaceutical industry that is the main source of therapeutic information, since it is such industry that has the best knowledge of the products manufactured by it. Within this context, we believe at the European Pharmaceutical Law Group that it is essential that Direct-to-Citizen Information (DTCzI) becomes a fundamental health right by the end of the first half of this century.

For this purpose , it would be necessary to recognise in the near future that health is an individual right of every person, who should be entitled to receive non-promotional information in order to take their own decisions, and who should not be left exclusively in the hands of other stakeholders (the Authorities, industry, health professionals, etc.). Health authorities should strive to protect our health rights, providing real safeguards, but they should also leave the way open once and for all to the real and affective involvement of the "citizen", irrespective of whether or not they are eventually the "consumer" or "patient". These subtle differences of perspective are extremely important, since the application of one set of legal provisions or another depends on the legal status that is given to us, having significant implications.

At the moment, the patient, and not the citizen, is placed at the centre of our national health systems, but brandishing the maxim "everything for the patient, but without the patient". This situation needs to change.

In Spain, the General Health Act (Ley General de Sanidad) implied a shift in direction with respect to the health rights and obligations of citizens. Other laws such as the Medicines Act (*Ley del Medicamento*), the Act governing the Cohesion and Quality of the National Health System (*Ley de Cohesión y Calidad del Sistema Nacional de Salud*), and the Patient Autonomy Act (*Ley básica reguladora de la Autonomía del Paciente*), have taken further steps to ensure the fairness of health care, but from the point of view of health information, they have only addressed the issue of clinical information, leaving to one side –more or less intentionally- any matters related to therapeutic information, information on biotechnology and information relating to the human genome, as if such information had no relevance whatsoever for citizens and their health. In this connection, we are concerned that European legislation would seem to be moving in the same direction, albeit occasionally more subtlely.

Aside from any current discussions of a more or less philosophical nature that may be engaged in with respect to the scope of the principle of free will of the individual, the reality shows a limited implementation of legislation in this regard. The principle of free will has never meant, and does not mean now, the "right to do whatever I want", but neither can it mean "let them do whatever they want with me". It is necessary to find a balance, so that both the right to information on health and the right to exercise our free will are real and effective, and not merely "items on the agenda".

The Constitutional Law of countries of the European Union recognises the right of citizens to express their wishes and take any decisions with regard to their health. The right to reject treatment is recognised by law, and therefore the wishes of the individual must also be respected.

The problem is that in order to take informed decisions, accurate, adequate and truthful information must be available. This has been achieved to a certain extent with respect to clinical information, but as far as information on medicines (therapeutic information) or information on biotechnology or the human genome is concerned, it is still only a distant vision that needs to be realised.

It is for this reason that we at Eupharlaw are demanding the right of each individual to receive therapeutic information that is accurate, adequate and truthful: "accurate" insofar as it does not contain erroneous data, is based on scientific evidence and is up-to-date; "adequate" insofar as it must be sufficient (and not excessive) and understandable for the recipient; and "truthful", insofar as it must not be false, misleading or exaggerate the truth.

II) THE REAL SITUATION

In Europe, in spite of directives such Directive 2001/83/EC, known as the "Community code relating to medicinal products for human use", and important subsequent amendments thereof (Directives 2003/63/EC, 2003/94/EC, 2007/24/EC and 2007/27/EC), neither the definition nor mechanisms for the communication of therapeutic information have been addressed at length, although the issue is now starting to be discussed with respect to the applicable terminology.

Following numerous serious cases of adverse effects on the health of citizens, such as those caused by "super drugs" such as Vioxx, Celebrex, Lipobay, Baxter's dialyzers, etc., there is no doubt that we must consider the need to establish new quality requirements with respect to the manufacture of medicines for human use and the information provided. However, this will not be sufficient, as the task of supervision and monitoring during the procedure for the registration of a medicine does not imply a total guarantee, as is shown by the continual mistakes made by all of the existing Medicines Regulatory Authorities, including the EMA (European Medicines Agency) and the FDA (American Food and Drug Administration).

Since the rejection of the proposal for amendment of Directive 2001/83/EC in 2002, which sought authorisation for the advertising of prescription medicines for three groups of illnesses (AIDS, diabetes and broncho-pulmonary illnesses), the industry has carried out numerous studies to weigh up the advantages and disadvantages that such advertising would have for the health of citizens and other stakeholders. Probably, the industry failed to originally address such possibility with sufficient care and realism, giving priority to business interests and its short-term realisation, at a time when the other stakeholders and society as a whole were still not prepared.

In our opinion, it is the pharmaceutical industry that has the obligation to provide the necessary information, as it is the original source of such information. However, it must do so correctly and in an understandable manner, primarily through the patient information leaflet. If it wishes to provide information through other media such as the television, general interest or specialist magazines, internet, etc., it must focus on

ensuring that "informing" does not mean "advertising" its products. Such information must not be provided "en masse", but as a response to a prior request for therapeutic information made by the citizen/patient, and must be based on a prior process of educating the citizen with regard to their illness and its possible treatments. Furthermore, advertising should not be used as an enticement, given that the medicine should only be used when the person really needs it, as its use always implies certain risks. Therefore, a medicine should not be held out to the public as a harmless product, nor should its unnecessary usage be encouraged.

IV) THE EUROPEAN UNION OPTS FOR DIRECT-TO-PATIENT INFORMATION

In 2002, the European Parliament rejected outright the possibility of legislation allowing for the direct advertising of prescription medicines to the consumer (DTCA). Now, the matter has once again been submitted to consideration, in accordance with the provisions of article 88a of Directive 2004/27/EC. Australia, Canada and South Africa have already reviewed their position and will continue to prohibit such advertising.

This holding back of the project for DTC advertising in the EU has not been received well by the pharmaceutical industry, and therefore an attempt is being made to reconsider the issue from a new perspective, such as the concept of Direct-to-Patient Information (DTPI). Although this approach is much more commendable than the previous initiative, from the point of view of the legal concept of "Therapeutic Information" and the rights of the citizen/patient, this will not give sufficient protection.

With this approach taken by the pharmaceutical industry, the aim is to enable information to be provided directly to the patient so as to inform them regarding its prescription drugs, without any intention of advertising such drugs. For this simple reason, the pharmaceutical industry would be a source of therapeutic information in the sense of article 88ª of Directive 2004/27/EC, when it refers to "the information source's liability", and would have to assume its part in such liability.

This way of approaching the issue, no doubt as legitimate as many others, in my opinion comes up against an insurmountable obstacle, on account of its lack of realism, which would hinder its future implementation. The problem with this approach is that it does not differentiate between "clinical" information and "therapeutic" information, and intends the doctor to be the only channel for the communication of information – as has been the case until now - and for the doctor to endorse information with which he/she is not familiar from the start, since it is the pharmaceutical industry which has produced such information and which therefore has a better knowledge thereof. This is especially relevant in the case of the prescription of new medicines, and their possible foreseeable or unforeseeable adverse effects.

Consequently, at the European Pharmaceutical Law Group we have taken the lead in this regard for many years, proposing more objective and realistic information on medicines.

At Eupharlaw we believe that the new concept of therapeutic activity makes it necessary to specifically define the concept of Therapeutic Information and to set forth specific legal provisions governing such concept separately from those relating to clinical information.

In addition, it is necessary to determine who should be the accountable stakeholders, as well as their respective duties, bearing in mind at all times that, if they so wish, it should be the citizen/patient who must decide on the therapeutic alternative. The doctor cannot continue to play a paternalistic role, taking decisions regarding the health and illness of the citizen without the real consent of the latter. Likewise, he/she cannot ignore the role of other health professionals, whose involvement is vital for the provision of information on medicines.

We believe that the cooperation and co-liability of stakeholders are essential tools for improving the efficacy of medicines, reducing their adverse effects and increasing treatment compliance by the population.

In this regard, it is important to distinguish between the terms “new” and “innovative” with respect to medicines, as not every new product means a step forward in therapeutic terms. New products are produced that are only new from a technological or commercial point of view. For this reason, it is essential to compare the new product with already existing products, and not with a placebo, as has been the case until now. Furthermore, medical trials should use a sample of the population that is sufficiently representative of the illness for which the medicine is intended. In short, the trials must actually show the efficacy and safety of the products in order to be able to make any claim with regard to their properties.

Within this context, it is vital that mechanisms are established in order to truly differentiate between “information” and “advertising”. In our opinion, “The legal Proposal on Information to Patients” of the European Commission is a step forward, providing that real safeguards are put in place to ensure its implementation.