

Challenges in the chain of responsibility for the efficient use of medicinal products – The position in Spain

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The *efficient use of medicinal products* has become a fashionable topic in recent times to the point that the proposed bill that purports to substitute the *Law on Medicinal Products*, developed by the Ministry of Health and Consumption, is called the *Law on the guarantees and rational use of medicinal and healthcare products*. It is not that this is not important, but what must first be addressed is on who does it depend or on who does this rational use impact? It seems that those most directly affected are the patients, but they are not the only ones and, in fact, they are the last ones in the chain as prior to them we find Health Authorities (on a national and regional level), the prescribers (doctors and vets) and the dispensers (pharmacists), without forgetting the important role that other health officials play in overseeing the administration of medicinal products (helpers or general auxiliaries). Let us proceed to examine this further.

1. The Health Authority

It is directly responsible for the authorisation of a medicinal product, including authorising it onto the market in accordance with the system established by the European Union, which is applied by Member States in their area or territory and which we understand to be quite acceptable although, as everything, not perfect, as it has its defects and problems, mainly in its practical application in each Member State. For example, the discussion on the sale price delays, in many cases, the effective launch onto the market of the products, which in turn means that the citizens of that country cannot have medicinal products available in another, or other, EU countries and forces medicinal products to be imported from abroad.

One of the big problems in Spain is the proliferation of new products, in theory, identical medicinal products, and particularly generic ones. Commercial laboratories of generic products have proliferated incommensurately and the majority are simply commercial laboratories that order the manufacture from the few remaining third parties. In the last “Catalogue of pharmaceutical specialities” by the General Council of Official Pharmaceutical Professional Colleges (2005), we can deduce the number of existing Generic Medicinal Products from various medicinal products:

Aciclovir 250 mg, 25 tablets (11); Amoxicillin 500 mg, 12 caps.(15); Azitromicine 500 mg, 3 t.(20); Captopril 50 mg, 30 t.(18); Cefotaxime IV 2 g, ing. (15); Ciprofloxacin 500 mg, 10 t.(25); Claritromicine 500 mg, 14 t.(18); Enalapril 5 mg, 60 t.(24); Fluoxetine 20 mg, 14 c.(32); Omeprazol 20 mg, 14 and 28 t.(36); Simvastatine 10 mg, 28 t.(24)

Without doubt, proliferation is a serious problem. It is utterly impossible for the pharmacy office to be able to make available all the new commercialised products (including the wholesale entities) so it is obliged to select a few (or simply one) and to substitute the prescribed one or to stop dispensing or to defer dispensations until receipt, if it locates it, all to the detriment of the patient. But if the prescription is made out by the *International Nonproprietary Names* a practice which is becoming more common in some Autonomous Communities due to approval and even pressure on doctors by health authorities, the pharmacist has a free choice. All this causes inconveniences that would not exist if there were only one new product – there is a possibility that despite being theoretically bio-equivalents in reality this is not completely the case due to the presence of different technological auxiliaries which may impact differently on patients (allergies or other adverse effects), situations that have happened with the same product when the manufacturer has been changed and they have not strictly maintained the same composition and technology. The best solution would be the existence of a single product (with one sole manufacturer) for each medicinal product, pharmaceutical form and dose, maintaining the continuity of the composition of all the components and in the manufacturing technology; naturally subject to strict satisfaction of the market needs. It seems impossible to achieve due to free trade and competition principles, but there are states that achieve it, thus there must be formulas to regulate it. The health of citizens should be above principles of free trade and free competition: everything should be susceptible to regulation if with it, we achieve a better use of medicinal products and in turn improve the health of citizens. If the Law on Patents limit the use of a pharmaco for several years in order to protect the security of the discoverer, why can it not be regulated for more years, in fact every year, on the grounds that it is better for the security of patients?

Another problem in the hands of the Health Authority is the old medicinal products that are still on the market, without any evidence that they are of any use apart from for the placebo effect. It would seem that the logical thing to do would be to re-evaluate them; unfortunately it is not that easy, amongst other reasons because it would cause negative results in the majority of cases. The adequacy of eliminating medicinal products must be considered, especially those that have a market covering their purpose (even if subjective) and are cheap and generally not financed by public funds.

2. The prescribers

The prescriber should not be limited to writing a prescription and handing it out, without any other action, which happens all too often. He should give instructions

or an explanation on the medicinal product to help the efficient use of medicinal products. It must be recognised that there is not much time in consultations which complicates this but with some will it can be achieved.

3. The pharmaceutical dispenser

This is a key element in ensuring the efficient use of medicinal products by the patient. Pharmaceutical attention, ever more stretched, is a good point of contact to instruct patients on the effective use of medicinal products, which can be increased if information is divulged, such as diagnosis knowledge (this will be stressed in the section dedicated to prescriptions) or medicines are personalized dispensed (isolated cases). Their role should not be underestimated in correctly answering questions, collecting medicinal products that are unused, avoiding the dispensation of incorrectly self-prescribed medicines, handing over medicinal products to strangers, using products past their sell by date or eliminating products being dispensed in a way that contaminates the environment. Personalised dispensation, particularly to the elderly, has greatly helped the correct use of medicinal products and should be promoted from all healthcare spheres. Promoting and supporting every aspect of this, from availability of resources, solutions for pharmacists to help with their workload and resolving problems without resorting to technical-economic solutions will help.

4. Auxiliaries or healthcare assistants

The correct intervention of technical-healthcare auxiliaries in the administration of certain medicinal products and visiting patients can help the correct use of medicinal products if they take an interest, as they usually do, in the whole treatment and advise about the correct following of the treatment.

There are general issues that impact, in some way, in the effective use of medicinal products, which shall now be considered.

a) Health education of patients

Health education of patients is essential. If it were correct there would be no need to insist on the correct use of medicinal products. Starting with primary school children, they should be taught at least what a medicine is, the good it provides, the good it can bring if it is used correctly and how harmful it can be if it is used incorrectly. There is no question that the first and best educators of children are teachers and that is where the process should start: information to teachers, awareness campaigns, support from the Health Authority and corporate healthcare bodies, information leaflets, etc. However, the information should not only continue in all stages of education, but also outside of it, for example through pharmacies which have an extraordinary

influence on society, helping them (as they have done and do) through information leaflets, signs, etc. The Law on Medicinal Products (1990) that states in its article 84.5 “*Health Authorities will complete health education programmes on medicinal products directed towards the general public*” is of little use if it is not carried out on a permanent basis. Nor is it of much use that the Draft Bill on the guarantees and rational use of medicinal and healthcare products includes it in its article 74.5 and adds “*promoting acts that favour a better knowledge of medicinal products to improve therapeutic ends, avoid risks derived from incorrect use and raise public awareness of the economic value of medicinal products*”, if it then is not translated with effective practical measures.

b) Training of professionals

The training of healthcare professionals in Spain has not been resolved, and probably never will be. In general Universities are quite dissociated from the professions and, therefore, it is difficult to permeate their wishes or aspirations. However professionals themselves and their regulatory agencies do not always get their approaches and objectives right either. It would be helpful if both sides adopted flexible positions, were involved in a lot of dialogue and built the future together. The syllabus (curriculum) should not just be left to the decision of the professional bodies, that are too pragmatic or “practical”, nor should it be solely left to the educational institution which can be dissociated from professional reality and takes decisions very slowly. Studies should evolve and we should find an equidistant solution between the two, professional and educational.

However, worse still is continuous training. There is an urgent need for professionals to be trained on the advances and happenings of each moment. The medicinal products and treatments today are beyond recognition compared to the treatments a decade ago, without mentioning two or three decades before then. Healthcare professionals do what they can to keep their knowledge up to date but it is obvious that it is not enough. Books are expensive and they lack the time to read them; subscription to journals is onerous and their publication is getting harder due to a lack of support: the pharmaceutical laboratories used to edit their own journals that doctors received, which were of great help for continuous training who does not remember *Medicamenta* with its medic and pharmaceutical editions, edited for so many years by the distinguished professor Lain Entralgo, D. Pedro? They have disappeared and the laboratories have transferred their help to independent journals by way of advertisements that have permitted them to scrape by, but each time they are further on the way to vanishing. What has the Government done to protect them or to promote them? Why has it not promoted them by applying, for example, a proportion of what it has collected through “taxes” from pharmacists? The future finds itself reduced to research on the internet, which is highly time consuming, for professionals keeping up-to-date and the sources are not always reliable, as often articles are based on the sensation they will cause rather than scientific facts. As for conferences and short

courses, it is true that they are available but not as regular as necessary and lack the required correlation between topics.

The Law on Medicinal Products of 1990 states in its article 84.1 that “*the relevant public authorities in the scope of healthcare and education shall direct their acts towards the promotion of university training and post-university continuous and permanent training of medicinal products for healthcare professionals, particularly the promotion of pharmacology and clinical pharmacy.*” Article 74.1 of the Draft Bill of the Law on the guarantees and rational use of medicinal and healthcare products transcribes the former on its first point and modifies the second to transform it into “*knowledge of pharmacology, clinical pharmacy and training in the rational use of medicinal products shall be considered areas of priority.*” Therefore there is no lack of legislation but it has no practical effect. Some countries impose a requirement of voluntary independent study and the *acquisition of credits* to be able to continue to work as a healthcare professional. This has advantages that, probably, outweigh the inconveniences it imposes. Spain has never adopted such an approach and if it were to do so, it would have to regulate the process to be able to achieve the objective. The Government would need to introduce a measure for universities and/or professional bodies in order to render the credits indispensable, but at the same time, enabling professionals, particularly in public healthcare, the realistic chance of obtaining them. Today, due to information technology, independent study is a much more attractive proposition but it needs to be put in place, guided and encouraged and given some form of continuity. Pragmatic “political” statements, referred to above, are of no use. Progress and the will to improve are achieved by putting ideas into action. Why have these not yet been put into practice?

c) Prescriptions

Harmonisation of prescriptions, of at least the principle features, was needed in the European Union. It is a difficult problem due to the extreme nationalism of the Member States but at the same time, perhaps it has not been attempted with great enthusiasm. The *Association Européenne de Droit et Economie Pharmaceutiques* attempted it in 1998 (Seville 26th and 27th of April; a discussion of this issue took place at a committee prepared by Aulois, Bel-Prieto, Tabutiaux, Stanford and Locher) but the proposal made fell on deaf ears. Thus it does not seem too difficult to reach an agreement, although the Spanish experience is discouraging. The Royal Decree 1910/1984, of the 24th of September (of more than 20 years ago) that regulated it, relied on the appeal against it by the *General Council of the Official Colleges of Medicine*, and despite their rejection of the judgement of the Supreme Court of the 4th of February 1987 and the order to carry it out in the Order of the 15th of June, published in the *Boletín Oficial del Estado*¹ of the 3rd of September of the same

¹Daily Spanish Government publication in which new laws, directives and executive decisions are published.

year, it was never applied with the exception of the National Healthcare System that established its own models; private medicine never accepted it and the Government never did anything to enforce its application. There are now some autonomous communities that have established or are going to establish their own models and we fear that it will be another area where the freedom of autonomy will lead to situations as disparate as is the case with pharmaceutical organisation.

Now there is work being done towards the introduction of an electronic prescription, but this task is not an easy one. The autonomous communities want their ideas to prevail and some are in quite advanced stages. However, any individualist or individual initiative is believed not to be in the best interest of the State as a whole.

One of the problems that need to be addressed is the diagnosis. Should the patient's diagnosis be on the prescription or not? It seems indispensable for an accurate follow up and the dispensing pharmacist requires it to dispense correctly and, therefore, achieve effective pharmaceutical attention; but then we collide with the law of data protection and, once more, secrecy seems to prevail, not to be confused with professional confidentiality, above the need to provide good healthcare assistance to the patient.

c) Health insurance card

If it is difficult to achieve consensus on the subject of prescriptions, it is even harder in relation to health insurance cards. Some autonomous communities have introduced them and they require it to be able to have any healthcare assistance, including the dispensation of medicinal and healthcare products. But now, it is only a personal administrative document in a way similar to the DNI card² but has a magnetic strip. It identifies the individual on the Healthcare System and logs the services used. However, it is not available in the majority of autonomous communities and is not interchangeable with the communities that do have it as they are not prepared to see patients from communities other than their own. Will these barriers be brought down? Today's technology could easily do this but there is a lack of a political decision to do so. What truly would be useful would be a *global health insurance card*, in other words, a card not limited to administrative details but also containing clinical details that would allow integral healthcare knowledge to be available. It would not be difficult to achieve but seems far in the future yet.

²The Spanish *Documento Nacional de Identidad* is a laminated plastic ID card which all Spanish nationals over the age of 14 are required to carry and be able to produce to the police on request. It includes a photo, fingerprints and personal details.