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Medical visits and Covid-19

¿May medical visits be restricted? What about on-line visits? Medical visits face new challenges in the "new normality"

An important and highly regulated activity

Medical visits are one of the main and most important means that pharmaceutical companies may use to provide information about their products to healthcare professionals qualified to prescribe or dispense them. Moreover, visits are important because they allow company representatives to collect information about the use of the medicinal products, which they must transmit to the scientific service of the company.

Its basic legal regime is established by Royal Decree 1416/1994 on advertising of medicinal products for human use, by which the provisions of Directive 1992/28/EEC (nowadays included in Directive 2001/83/EC) were transposed into Spanish law. Together with this basic legal regime, several other local rules impact on medical visits in Spain. In many cases, regional health authorities who are competent to organise their own healthcare services, have issued instructions or service orders regulating the activity of medical visitors. These legal instruments have the main purpose of regulating the impact of medical visit in healthcare practice at hospitals. The instructions normally deal with logistic issues and establish the conditions under which these visits may be carried out at public hospitals or other healthcare centres.

The recent order approved by the Healthcare Department of the Basque Country on 10 February 2020 is an example of these norms, which must always respect the basic rules established under Royal Decree 1416/1994 and the basis for their homogenous implementation as approved by the Interterritorial Council of the National Health System.

Restrictions on medical visits

The health alert situation created by Covid-19 has resulted in administrative authorities adopting exceptional preventive measures with the objective of protecting public health, fighting the spreading of the virus and making the health system stronger. Among these measures, some authorities have restricted the activity of medical visitors.

In view of these restrictions some questions arise. Do they affect only public hospitals or also private ones? Do the limitations relate to personal visits or also to on-line ones? Are these restrictions necessary and proportionate?

In respect of the first question, our view is that these communications only affect healthcare professionals when acting within the sphere of competence of the administrative authority who issues them.

Competent authorities may prohibit medical visits to public hospitals or healthcare centres under their jurisdiction, but they cannot prohibit medical visits to healthcare professionals in private clinics or offices.

As regards on-line visits, the answer is not black on white. In some regions, it has been said that on-line visits fall under the general concept of

medical visit (for instance in the Basque country, where article 3.1 of the above mentioned Order states that "there shall be considered medical visit ... all forms of electronic communication that the pharmaceutical industry may use to offer information about its products to healthcare professionals with the purpose of exerting some positive influence in their prescribing decisions").

In these cases, the restrictions to personal visits may also affect on-line ones, as it happens in the Basque country. In other regions where no specific rule has been adopted, the issue will require a case-by-case analysis. Neither European or national basic legislation (Directive 2001/83/EC and Royal Decree 1416/1994) offer any definitive answer to the question.

This brings us to our third query. Are these restrictions necessary and proportionate? In our opinion, the analysis of this question obliges us to refer to Law 25/2009 on the freedom of access to services activities and their exercise, also known as "Omnibus Law". This law introduced a general principle of great importance in our administrative legal environment. This principle is currently contained in article 4 of Law 40/2015 of the legal regime of the public sector, which states that "public administrations which in the exercise of their competence, establish measures that limit the exercise of individual or collective rights or require the fulfilment of conditions in order to develop an activity, must apply the principle of proportionality and elect the measure which is less restrictive, motivate its need for the protection of public interest and also justify its adequacy to achieve their objectives, without it being possible to establish discriminations in any case".

In our view, any limitation of medical visits (a legally recognized mechanism through which pharmaceutical companies may establish relationships with healthcare professionals in order to convey information about their products and services) must be motivated and be proportional to the objective it aims to achieve. In this respect, authorities must be very careful and should avoid that restrictions that may be in place during the pandemic with the purpose of protecting public health remain in force beyond this period.

E-communications and privacy

It is a fact that electronic communications between industry and healthcare professionals are going to have special relevance in the future.

In this context we should not forget that companies may only send electronic promotional communications to those healthcare professionals who have expressly agreed to receive them. The consent of the healthcare professional is a key element to ensure that promotional communications comply with applicable law. How must this consent be? This is a question that has recently created a lot of interest in healthcare professionals, most of which have little time to dedicate to medical visitors and whose e-mail inboxes are full of e-mails.

Under the rules that govern personal data such as the GDPR and Law 3/2018 on the protection of personal data, consent must be unequivocal and must be expressed through a clear affirmative action or declaration. the rule is that only a "YES" is a "YES". It is necessary to get a "YES" to assert the existence of consent.

On the contrary, it is not acceptable to rely on tacit consent (i.e. send a communication, alerting the recipient that absence of a negative answer from the professional will be understood as consent to receive commercial communications).

At European level, the European Data Protection Board has recently issued guidelines 05/2020 on consent on the regulation 2016/679.

These guidelines which are an update of the ones that Article 29 Working Party adopted in the past, confirm the abovementioned criteria. In this sense the EDPB states the following:

- The consent must "be obvious";
- The use of opt-in boxes is valid (e.g. if you consent, tick X in the following box);
- The use of pre-ticked opt-in boxes is invalid (e.g. if you do not consent, untick the X from the following box);
- The silence or inactivity of the subject cannot be regarded as a valid form of consent.

Therefore obtaining unequivocal and express consent from healthcare professional is necessary to send promotional communications to them, it not being possible to relax this requirement at any time, not even in the present situation originated by Covid-19.