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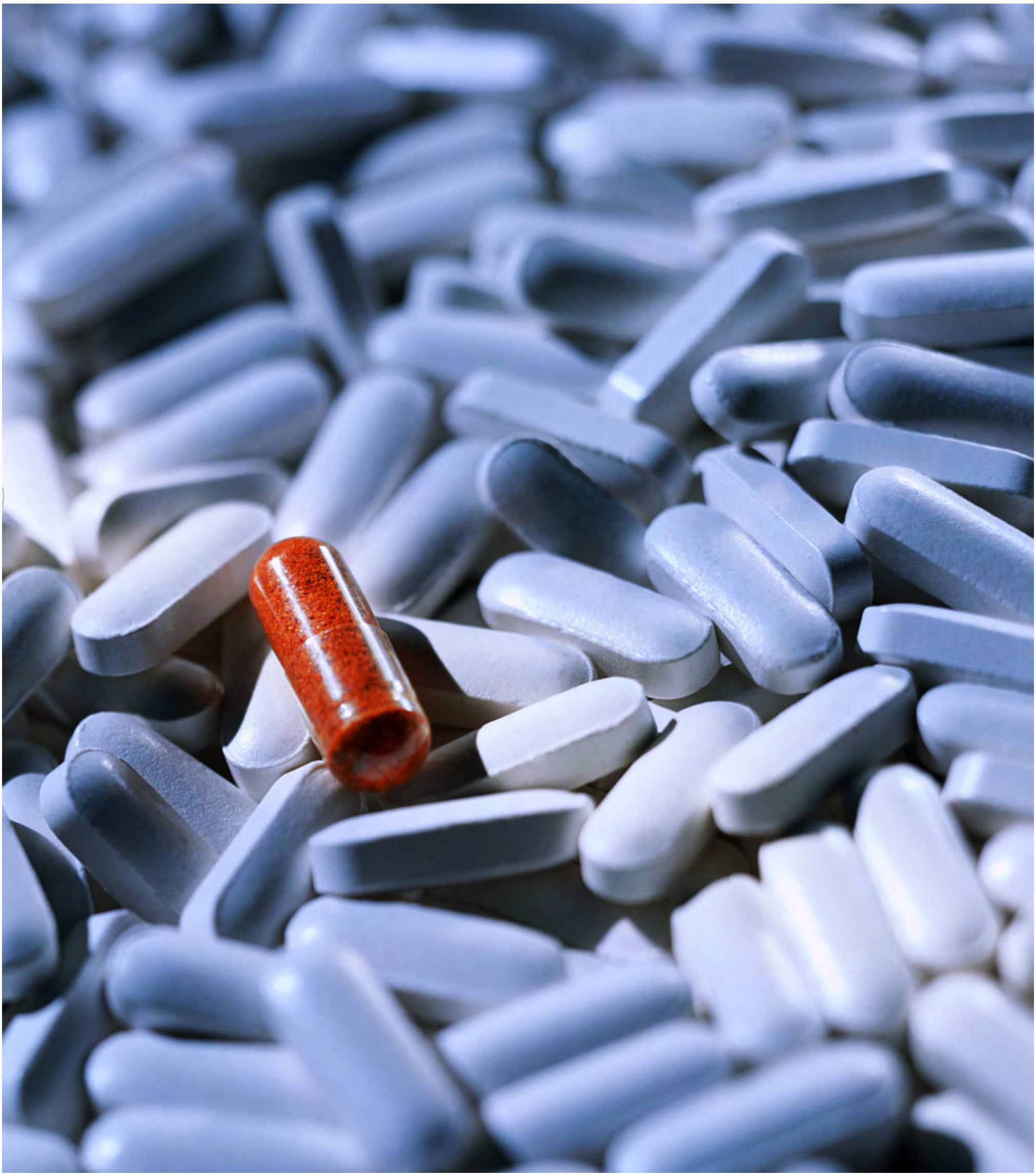
CORPORATE LiveWire

JANUARY 2014

BIOTECHNOLOGY & PHARMACEUTICAL SECTOR 2014



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Recent Issues Concerning The Pharmaceutical Industry In Argentina

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As you no doubt already know, the Pharmaceutical Industry in Argentina is a strictly controlled industry. Said control is held by the ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) and it spreads from the first authorisation of a laboratory to act as such in the country, moving through the authorisations to commercialise products, up to pharmacovigilance of products that have already been commercialised.

The general rule that regulates the pharmaceutical market is the law 16.463, issued on August 1964, but has been adapted through decrees, resolutions and dispositions. It is most accurate to suggest that the present regulation on the principal topics of the pharmaceutical market is defined by the Decree 150 issued in January 1992.

Regarding the authorisation for laboratories to commercialise theirs products in the country, it has been a long standing idea of those that issue the political regulations to promote the local manufacturing as much as possible. The general understanding is that laboratories must perform most of the manufacturing activities in their plants, although they might sub-contract part of the process with third parties. However, it should be noted that the quality control process should be made by the laboratory authorised by the ANMAT to commercialise the corresponding pharmaceutical product.

Some laboratories, acting within the scope of the Resolution 223, issued on April 1996, have been authorised to act only on commercialising pharmaceutical products; this is not manufacturing them but acting as importers and or mere sellers of products. Nevertheless, these laboratories, as well as all other ones, must have a quality control lab, a warehouse cleared by the ANMAT and a technical director responsible for the quality of the products that the laboratory commercialises.

As said, it is the intention of the regulators to promote the manufacturing of pharmaceutical products in the country. To such extent we might say that in practice it has been very difficult to obtain authorisations to only commercialise pharmaceutical products. Moreover it is the intention of the authorities to adapt the Decree 150 and Resolutions, with respect to laboratories to a new rule that classifies laboratories in different categories: (i) those entitled to register, manufacture and commercialise pharmaceutical products in their own facility and (ii) those entitled to register and commercialise pharmaceutical products without having a facility of their own.

Those laboratories authorised to register and commercialise products without having a facility of their own are obliged to comply additional requirements to those currently in force. These laboratories must have not only a quality control lab, but also additional labs and warehouses. These kinds of laboratories must also have clinical trials programs. They can delegate all the manufacturing process to laboratories that are only authorised to manufacture to third parties. Please bear in mind that these last comments do not correspond to legislation currently in force, but to bills that are under discussion at this time.

In connection to pharmaceutical products the, ANMAT continues to be the regulatory entity. All products, including OTC, must be registered and cleared for their commercialisation before the ANMAT. It is possible to import products, but the import should be made through an authorised distributor that has to comply with certain requirements such as to have a technical director, who will be responsible for the quality of the products imported to the country. It is also possible to import

products, not yet authorised for their commercialisation in the country, for "compassionate use". Such imports should be requested with the intervention of a doctor and the intervention of the ANMAT.

The registration of products before the ANMAT for products registered in developed countries should only comply with the validation of the original registration. Other products must perform tests in order to obtain clearance. Pharmaceutical products of a biological origin must comply with specific requirements.

The products known as "Over the Counter" products (OTC) have been the subject of several legal controversies during the last year. The common and publicly known way to sell these products was not only in pharmacies, but also in kiosks or other stores that kept them in small quantities. Moreover, certain pharmacies kept these products in shelves placed near the registers, available for any customer to grab and purchase them without consulting a pharmacist. However, during the past years by means of different judicial and administrative decisions, it has been forbidden to offer and sell OTC in places that are not authorised by the authorities as "Pharmacies". Moreover, even in the case of the pharmacies, the OTC must be behind the counter, controlled and delivered to the customers only by the pharmacist - in other words, the regulation became quite strict regarding what concerns to the commercialisation of OTC.

Another aspect in which the pharmaceutical industry has been quite active in recent times has been related to the Good Practices in the Commercialisation of Products. The control of the wording and information included in the promotional materials that are delivered by reps to doctors and even the public advertisement of OTC products has been under strict control. It should be noted that the inclusion of phrases such as "consult your doctor" are mandatory and phrases such as "the number one", "the better", "the most" have to be duly founded in serious reports and researches carried out or validated by recognised and important auditors and consultants in order to be included in promotional material.

Clinical trials of the pharmaceutical industry is another area in which ANMAT has been actively present in the past years, especially in matters related to the obtaining of the informed consent and the treatments for patients once the study is over. With respect to the first matter, ANMAT has been exercising a thorough control of the process in which the IP and the subinvestigators request the informed consent to the patients, the explanations given by the doctors and the documents they request before entering a person to a study. Regarding the second matter, ANMAT makes sure that the participant of a study knows that, once the study is over, the Sponsor of the study must provide access to the drug or treatment of the study –if it was beneficial for the patient- until it is covered by some other mean (such as Social Security Entities).

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