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Latest issues in Argentine Pharmaceutical regulation

By Emilio Nicolás Vogelius

The Pharmaceutical Industry continues to be a highly regulated and controlled activity in the Argentine Republic.

The principal regulation that continues to rule the activity in the area is still the law number 16,643 issued in 1964. The original intention of the law was to stimulate the manufacturing of pharmaceutical products in the country, thus creating a local industry that could respond to the needs at the time.

Science has developed from 1964 up to nowadays and the Pharmaceutical Industry faces new challenges that are grounded in different origins, such as the development of science itself where the increasing participation of biological products has enlarged the scope of pharmaceutical products. Jointly with this scientific development, the appearance of biological products with background has also created specific regulations, mainly concerning the registration of such products before the different public authorities in charge of authorising the commercialisation of pharmaceutical products within the country. There are certain rules that specifically refer to the registration of biological products with background based in the registration of a biological product that are aligned to the FDA and EMA regulations, although specific guidelines are still lacking.

A second challenge that affects the pharmaceutical industry, although not unique to it, is related to the economic support that Social Security entities usually need to afford the cost of the products that have increased due to several reasons, such as the sophistication of the manufacturing procedures and the products themselves, plus general economic circumstances that could affect the country or specific regions. Expensive products and those for chronic sickness are usually free for the patients.

In connection to the matter above described, Argentina has developed a system by which the Pharmaceutical Industry, the Commercialisation Sector, Social Security Organisations and the patients themselves collaborate in different proportions to make the products accessible to a larger number of people. This is, of course, a broad description of the system that recognises exceptions, mainly in those cases in which the access to medication would be impossible for a certain patient, or for the treatment of specific diseases.

It is worth mentioning that the main streams of economic support in the access to pharmaceutical products are public entities, both national and provincial, plus other economically self-sufficient public entities, such as PAMI which assists in the needs of retired people. There are also entities that are linked to unions or professional institutions and there is a private sector that works in a way similar to what could be called medical insurance coverage. In certain cases, the patient is required to collaborate, paying part of the price of the product.

We consider it important to highlight that, due to the existence of a system such as the one mentioned in the paragraph above, which imposes the use of the regular commercialisation channels for the patients to collect their products, it was possible for the Pharmaceutical Industry to keep the same prices for the same products across the country using the private net of distribution for the sale of those covered by these kind of participation in social security agreements.

We ought to mention that despite these programmes that concentrate the major sales of pharmaceutical products in the country, the government keeps in place specific programmes for those who are unable to afford any kind of health protection. Additionally, it is worth mentioning that other channels for the sale of products, such as public bids are kept in place for acquisitions in bulk, especially in hospitals and big health care units.

A third challenge originated in economic politics is related to the strict informal price control that the public authorities have put in place for the sale of pharmaceutical products. This

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measures those who strictly control the import of goods, and has created a difficult environment for the development of business within this sector.

Moving into a different area of concern we ought to point out that the public authorities have amended the criteria for the granting of pharmaceutical patents. Such amendment was established by a Joint Regulation (Nº 118/2012 and 107/2012) issued by the Ministries of Health and Industry and the Instituto Nacional de la Propiedad Industrial (INPI – Argentina Patent Office).

The amendment sets Guidelines for Patentability Examination of Patent Applications related to Pharmaceutical Inventions. It is exclusive for applications submitted in the pharmaceutical area and includes applications that have already been submitted to the INPI and are still pending. The application of such guidelines/ instructions could imply the refusal of pharmaceutical patents for; compositions, dosage, salts, esters and ethers, polymorphs, analogy processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims.

The pharmaceutical industry, mainly the one related to research and development, has initiated a lawsuit, the purpose of which is to annul the effects of such Joint Resolution. To such extent a judicial action was initiated grounded in the fact that the announced change in the patentability criteria infringes the Argentine Constitution, in its Sections 17 and others. Section 17 expressly determines that every inventor is the exclusive owner of his work, invention, or discovery for the term granted by law.

The Joint Resolution referred above also infringes the TRIPS Agreement, mainly Section 27.1. which establishes that: every author or inventor is the exclusive owner of his work, invention, or discovery for the term granted by law, bilateral agreements and the local patent and administrative laws. A broader description of the action would clearly exceed the purpose of this brief. Besides, there is a judicial action in place now and to extent the description made is a matter now subject to a judicial opinion and decision.

Finally we ought to mention that regulations that tend to put in place a traceability/ serialisation programme have been put in place by the local Board of Health.

Emilio N. Vogelius *is a senior corporate law partner of Estudio Beccar Varela, being fluent in Spanish and English*

He currently heads the Arbitration Team of the firm and the Life & Sciences Team.

He headed the drafting of the Life & Sciences Argentine Chapter of the Practical Law Multi-jurisdictional guide 2012 published by the Practical Law and the Expert Guide - Biotech & Pharmaceuticals for 2014. He is also the co-author de World Intellectual Property Rights and Remedies published by Oceana Publications Inc. (2001) and the co-author of the Argentine Chapter of the book "International Arbitration in Latin America" published by Kluwer Law International (2003).

Mr. Vogelius has been awarded as the Exclusive winner of the General Corporate category for Argentina of the International Law Office Client Choice Awards 2010