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THE DEVIL IS IN THE DETAILS

(or: "sort of fixing it")

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Until 2001 ANVISA used to authorize the transfer of pharmaceutical products registrations that are subject to Sanitary Surveillance, from its holders to third parties through a specific procedure. The main regulatory requirements for such transfers were: **(1)** that the successor held all, legal and regulatory, authorizations and license required to operate in the market and that, **(2)** all conditions approved in the registration and post registration data submitted for the product object of the transference remained unchanged during the transference procedure.
It is important to point out that, neither Law 6.360/1976 and its amendments, nor Decree 8.077/2013 (or Decree 79.097/1977 in force up to August, 2013) that regulate Sanitary surveillance in Brazil, impose any restriction or specific rule to the transference of pharmaceutical products registration, but only regulate the granting of the registration.

Since December 2001, through Resolution RDC 221/2001, ANVISA decide to regulate the procedure for the transference of product registration also within the scope of commercial operations holders of the product registrations, restricting the concept of "commercial operations" to the cases of mergers, acquisitions and spin-offs.

The updating of Resolution RDC 221/2001, that is, Resolution RDC 246/2002 and Resolution RDC 22/2010 have, not only maintained the existing restrictions, but also the bureaucratic constraints and the workload associated to it, with a negative impact on ANVISA and on the pharmaceutical companies. Although ANVISA may secretly desire, it does not have and should not have the Power to interfere on the way companies structure their commercial operations, unless they represent, even if potentially, a sanitary risk.

The regulations mentioned above simply disregard the most common form of transfer of pharmaceutical products, that is, the sale and the licensing of the product. The failure to include these operations among those that allow the transference of the registration has created a regulatory vacuum.

The peculiar and kafkanian solution found by ANVISA was to allow that, in the cases of commercial operations involving the licensing of the product, was for the parties involved in the operation to, concomitantly request:

(1) the canceling of the registration by the licensor and.

(2) the filing of a new registration (including the entire registration package (already filed at ANVISA for the original registration) by the licensee.

This "solution", more than generating unnecessary stress, with a possible product shortage in the market if the cancellations and the new registration do not occur simultaneously, also required a number of side agreements between the companies to guarantee the distribution of the product during the review of the cancelation and new registration procedures by ANVISA.

Considering that Resolutions RDC 221/2001, 246/2002, and 22/2010 as written, restricted the reality of business in the pharmaceutical segment, ANVISA started a procedure to review the mentioned norms, which was concluded in 2016 and officially enacted as Resolution RDC 102/2016.

However, Resolution RDC 102/2016 only partially corrects the existing restrictions on the procedure for transference of product registrations. The new Resolution, although authorizing the transference of the registrations, also in the case of "commercial operations" only includes within these operations those "resulting from the sale of assets or a group of assets" (article 4 item VII of the Resolution).

The new Resolution chose to ignore:

(1) that a considerable part of commercial transactions involving pharmaceutical products results in the Licensing of products and not in sale and purchase of products. In licensing operations, as there is no purchase and sale of the product, no transfer of assets results from the operation; and

(2) that a registration of a pharmaceutical product before the regulatory agency, from a legal perspective, is but a seal that authorizes the commercialization of the product and this "seal" will never be an asset of any company.

Is it reasonable to allow the transfer of product registrations only in the case of sale and purchase of an asset (the product) or in the case of mergers and acquisitions, consigning to oblivion licensing operations? In our opinion, no. This differentiation represents, in fact, undue interference in the management of the companies as the mere transference does not represent, in itself, a sanitary risk. Moreover, the present wording of the Resolution would not, in principle, even allow the transference of the registration in the case of a donation of a product from one company to the other.

If, any give product, duly approved for commercialization, that will maintain the same trademark, formulation, and manufacturer and the same therapeutic indications, becomes commercialized by a different company that also complies with all sanitary and regulatory requirements in force, what is the rationale for ANVISA to limit the possibilities of the transference of the registration to this or that legal operation?

ANVISA seems to have a latent desire to interfere in the form the companies choose to manage their businesses. Let us remember that in March of 2007 ANVISA enacted Resolution RDC 25/2007 that imposed unjustifiable restrictions to the outsourcing, by manufacturers, importers and warehousing services, of certain of their activities that, since then have obstacles and unnecessary costs that are surely reflected in the prices of the products.

RDC 25/2007, that should have been limited to the outsourcing of some production aspects, ANVISA also decide to restrict the outsourcing of warehousing and of quality control testing, in a clear interference in the management of companies' businesses. The Resolution sets forth, for instance, that manufacturers or importers can only outsource the warehousing of their products if they have their own warehouse. ANVISA has already publicly recognized, as mentioned by more than one of its Directors, that Resolution 25/2007 must be corrected. Presently ANVISA has all the tools necessary to regulate and inspect the sector, only based

in principle of quality, efficacy and safety; so it is absolutely unnecessary (and inappropriate), to interfere in the strategic management of companies.

ANVISA's Regulatory Agenda for the period 2017-2020, includes several relevant reviews of the regulation norms. The regulated sector continues to wait of the urgent changes.

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