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Brazilian government enacts law creating generic veterinary medicinal products

On 20 July 2012, Law No. 12,689, of 19 July 2012, was published in the Federal Official Gazette. This law seeks to create generic veterinary medicinal products in the country and to establish rules concerning the marketing authorisation of such products to be applied by the Ministry of Agriculture, Animal Husbandry and Supply (MAPA).

In brief, two new categories of veterinary medicinal products have been created in addition to the existing reference veterinary drugs: similar ("branded generic") and generic medicinal products for veterinary use.

According to Law No. 12,689/12, a similar veterinary medicinal product shall mean a medicinal product which has the same active substance, the same concentration and pharmaceutical form as the reference medicinal product for veterinary use, but which excipients may or not be identical, always being identified by its trade mark. Law No. 12,689/12 has apparently not considered a similar veterinary medicinal product to be interchangeable with the reference product, following the same terms of the legislation for drugs for human use.

By turn, a generic veterinary medicinal product shall mean a medicinal product which has the same active substance, concentration, pharmaceutical form, route of administration, posology and therapeutic indication as the reference medicinal product for veterinary use, with which the generic may be interchangeable, being allowed to differ only in characteristics related to size, form, expiry date, packaging, labeling, excipients and vehicles of the product, usually produced after the expiration or waiver of patent protection or other exclusive rights, its bioequivalence, efficacy and safety being proven by means of pharmaceutical studies, and always designated by the Brazilian Non-Proprietary Name (DCB) or, in its absence, by the International Non-Proprietary Name (INN).

As noted above, sometimes even if the veterinary substance has come off patent, other exclusive rights may in principle be enforceable against generics competitors, such as data protection exclusivity (DPE).

Indeed, in Brazil DPE is available for medicinal products for veterinary use, according to Law No. 10,603/02, and the following terms of protection may apply: I. for products using new chemical or biological entities, ten years as of the grant of registration or until the first release of information in any country, whichever occurs first, assuring protection for at least one year; II. for products not using new chemical or biological entities; five years as of the grant of registration or until the first release of information in any country, whichever occurs first, assuring protection for at least one year; III. for new data required after the grant of registration of the products mentioned in items I and II, the protection period shall correspond to the remaining period granted by the registration, or one year period as of the presentation of the new data; whichever occurs last.

Finally, in order to obtain marketing authorisation for a generic veterinary medicinal product, applicant must submit to the MAPA studies demonstrating bioequivalence with the reference medicinal product; therapeutic equivalence in the animal species to which its use is intended; and excretion rate, residue determination and withdrawal period equivalent to those of the reference medicinal product for veterinary product, when destined to animal husbandry.

Implementation regulations of Law No. 12,689/12 are expected to be enacted soon with details of the abridged application procedure for marketing authorisation of generic veterinary medicinal products, as the provisions of said Law will enter into force on 17 October 2012.

Please be sure that we shall keep you apprised of developments on this matter as they arise. In the meantime, please do not hesitate to contact us should you have any queries or concerns in this regard.