

Request for Public Comments by ANVISA (National Sanitary Vigilance Agency) on the Interchangeability of Branded Generic Drugs with Reference Drugs in Brazil

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The **National Sanitary Vigilance Agency (ANVISA)** is currently accepting public comments on the issue of whether branded generic drugs should be considered to be interchangeable with reference (innovator) drugs (reference drugs). According to the current regulations in Brazil, only non-branded generic drugs are considered to be interchangeable with reference drugs. However, ANVISA is now considering changing its regulations to allow branded generic drugs to be interchangeable with reference drugs. Such a change could have a significant impact on how drugs are prescribed and ultimately distributed to patients in Brazil. Moreover, this change would provide a boost to the Brazilian generic drug industry.

Currently, because non-branded generic drugs are considered to interchangeable with reference drugs, pharmacists in Brazil may, at their own discretion, substitute a doctor's prescription for a reference drug with a non-branded generic drug. The reason such substitution is permitted is because both Brazilian law and ANVISA allow for this interchangeability. If ANVISA were to change its regulations to allow branded generic drugs to also be interchangeable, a pharmacist would be able to substitute a reference drug with either a branded or non-branded generic drug. Therefore, this potential change would make it significantly easier for pharmacists to sell generic drugs because they would have a choice of providing a patient not only the reference drug but also branded and non-branded generic drugs. Previously, a patient could only purchase a branded generic drug if the prescribing doctor wrote a prescription for the branded-generic drug.

The Request for Public Comments #4 of October 18, 2013 (published on October 21, 2013) may be found by [clicking here](#). Comments can be submitted up until November 27, 2013 by [clicking here](#).

Please watch the BRIC Wall for further updates on whether ANVISA changes its regulations to allow branded generic drugs to be interchangeable with reference drugs.

This post was written by Gustavo de Freitas Morais of Danneman Siemsen and Lisa Mueller.

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