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ANVISA approves skinny labeling in Brazil

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On December 6, the Board of Directors (DICOL) of the Brazilian Food & Drug Agency (ANVISA) passed new regulations accepting an exemption to allow generics and branded generics (also called "similar" drugs) to remove patented uses from their labels – *i.e.*, skinny labeling. The change will come into effect 60 days after the amended text of Rule No. 47/2009 is published in the Federal Register.

The Brazilian Federal legislation does not allow skinny label or carve out (per article 3 of Law #6,360 of 1976) as it clearly establishes that a generic or similar (branded generic) must have the same therapeutic indications as the reference drug (i.e., both are a "*drug is that which contains the same active ingredient or ingredients and that has the same concentration, pharmaceutical form, administration route, posology and therapeutic indication and is equivalent to the drug already registered with the Food and Drug Agency, permitted to differ only in characteristics relative to size and form of the product, expiration date, packaging, excipients and vehicles*").

However, ANVISA's federal attorneys defended the changes suggesting that there would be no legal obstacle to having generic and similar labels with therapeutic indications diverging from the reference drug's label. According to the Federal Attorney advising DICOL, the ANVISA would have the power to regulate label text with the goal of broadening access to drugs. The draft change was then subject of public consultation from December 2022 to April 2023[1] over the amendment to article 14 of Rule No. 47/2009 to include an exception that: "[…] *the package leaflets of generic and similar medicines* ***may differ from their respective Standard Package Leaflets with respect to patented therapeutic indications or indications claimed in published patent applications***".

During the voting session on December 6, the ANVISA's Director President, Mr. Barra Torres, pointed out that the new wording of Rule No. 47/2009 is in line with the real goal of the national generics public policy**: to guarantee access to healthcare.** Mr. Torres stated that the removal of the patent-protected indication from the labels accompanied by the reason why such indication was removed, makes it clear that the removal is not related to the interchangeability of the drugs but is the result of an attempt to assure that commercialization is non-infringing. According to Mr. Torres, the exclusion of the patent-protected indication would work to solidify the owner's patent rights, as it would reinforce its right to exclude others form using the patented invention.

Mr. Torres also pointed out that this change will not result in encouraging off-label prescription, as off-label refers to using a drug for the treatment of diseases without scientific-based proof of its efficacy, and not merely prescribing drugs for therapeutic indications not listed in the product's

label. He said little to the effects off the change in the context of patent rights, aside from stating that advertising, marketing, and prescribing drugs for therapeutic indications that are not listed in its labels continues to be illegal in Brazil.

This represents a drastic change in the ANVISA's official stand on skinny labeling and could significantly impact the enforcement of "use" patents in Brazil.

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[1] Original Portuguese available here.

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