NEWS

DANNEMANN SIEMSEN

December 2014

# NEW RULES ABOUT NAMES OF PHARMACEUTICAL PRODUCTS ENACTED IN BRAZIL

Gustavo Piva de Andrade

In October 2014, the Brazilian Health Surveillance Agency (ANVISA) enacted Resolution RDC nº 59/2014 setting several criteria for the formation of names in pharmaceutical products.

The new rules are likely to cause a significant impact in the practice of the pharmaceutical industry. As a result, it is imperative that regulatory and IP professionals are aware of the new regulations enacted by the Brazilian health surveillance authorities.

The purpose of this article is providing an overview about Resolution RDC n° 59/2014 and commenting about the aspects which should be considered in the selection and adoption of drug names by a pharmaceutical company.

It also examines the Resolution from a practical perspective, shedding light on the interface between the new rules and some fundamental tenets of trademark law.

## REACH OF THE NEW RESOLUTION

Firstly, an important disclaimer: Resolution RDC nº 59/2014 makes clear, in its article 20, that product registrations granted under the prior rules will not be reviewed by ANVISA.

This means that the new regulation does not affect already granted registrations and will be limited to future registrations or to product applications that have not yet been approved by the agency.

Pharmaceutical companies, therefore, do not need to adequate existing product registrations to the new rules, which denote ANVISA's praiseworthy concern to protect vested rights.

## CRITERIA FOR NAMES OF PHARMACEUTICAL PRODUCTS

Resolution RDC nº 59/2014 brings two good news in respect to the names of pharmaceutical products.

The first refers to terminology. ANVISA has finally abandoned the term "trade name" to refer to the trademark of a pharmaceutical product. From now on, ANVISA will use the term "drug name", which is more appropriate than its predecessor, since the term "trade name" is commonly used as a synonym of "corporate name" in Brazil.

The second good new is even more important: the new Resolution revokes the "3-letter rule", according to which "the name of a medication could be similar to an already registered name as long as they differ in at least 3 different letters".

That rule was in blatant disagreement with traditional principles of trademark law. After all, there might exist confusingly similar trademarks that differ in three or more letters and sufficiently distinct marks that differ in just two.

Thus, ANVISA acted correctly in revoking the 3-letters rule and replacing it for section 7, sole paragraph, of the current Resolution. This section provides that "the intended drug name must have sufficient graphic and phonetic distinction in relation to the names of other registered drug products".

As seen above, the current rule mandates that the name to be registered before the agency must be graphically and phonetically different as opposed to prior registered names.

Although other criteria could have been added, this is unquestionably an improvement in respect to the prior rule, since the conflict assessment between two names should be done on a case-by-case basis and should not be governed by mathematics standards.

The new Resolution also provides that the trademark of the pharmaceutical product should preferably comprise only one word and its intended pronunciation in Portuguese must have direct relation with its spelling.

The existence of the term "preferably" indicates that the one-word structure is not mandatory.

The spelling rule, in its turn, indicates that ANVISA can reject names that can cause certain inconsistencies as to the way they are spoken or written.

For example, while seen the mark "THERAHAIR" identifying a medication used to stimulate hair growth, a Brazilian consumer familiarized with the English language would probably face no difficulty to pronounce the term correctly.

The same, however, would probably not occur with a consumer that is not acquainted with the English language, since when positioned in the middle of the word, letter "h" produces no sound in Portuguese.

It is precisely this kind of inconsistency that ANVISA seeks to avoid. As a result, it is imperative that pharmaceutical companies take this rule into consideration while selecting a new mark to be used in the Brazilian market.

## PROHIBITIONS SET FORTH BY THE NEW RESOLUTION

Resolution RDC n° 59/2014 provides, in its article 15, that trademarks of drug products and their complements cannot use:

- The suffixes of nonproprietary names recommended for each therapeutic class of pharmaceutical substances, even if in a position different of that usually recommended – this rule prohibits the use of suffixes recommended for each therapeutic class of the pharmacology, such as "-ADOL" for analgesics and "CICLOVIR" for antiviral compounds (according to the Manual of the Brazilian Nonproprietary Names).

- The parcel of the nonproprietary name of the drug substance, usually associated to certain active ingredient, when it is not part of the drug product composition – the goal of this rule is guaranteeing that the parcel of the non-proprietary name associated to certain active ingredient is only used when the active ingredient is present in the medication. The term "TAMOL", therefore, can only be used in connection with medications which have "paracetamol" as an active ingredient;

- Abbreviations, isolated letters, random sequence of letters, Arabic or Roman numbers, without clear meaning to the consumer or that do not have any relation to the features of the product – this rule is self-explanatory and can be used to prevent the use of terms and abbreviations that do not have a clear meaning to the Brazilian consumer;

- Names that do not correspond to the way the drug product is given – the goal of this rule is preventing confusion as to the pharmaceutical form of the drug or to how the medication is admi nistered. Thus, for instance, the terms "spray" or "lotion" cannot be used in connection with a liquid preparation administered orally;

- Words or expressions that may lead to the understanding that the drug product is innocuous, natural, exempt of or with reduced side effects, or that the drug product has superior potency and quality or unproven special properties – this rule prohibits the use of expressions such as "NATURAL", "SOFT" and "LIGHT" or any term that the may lead the consumer into doubt or error as to features of the medication;

- Words or expressions that emphasize a therapeutic action, without evidence upon clinical studies, and that may lead the consumer to believe that such drug product has superior therapeutic effect as opposed to another drug product of equal composition – this rule forbids the use of terms such as "MAX", "PLUS", "SUPER" in connection to variations of an existing medication, unless the manufacturer is able to prove that the variation is indeed superior to the prior one;

- Name of drug product that has been rejected due to efficacy or safety reasons.

Finally, the Resolution provides that, when evaluating other cases not included in the prohibitions, ANVISA may still reject the proposed name when it detects any sanitary risk to the consumer.

## FAMILIES OF DRUG PRODUCTS

Resolution RDC nº 59/2014 fortunately embraces the concept of families of drug products. It provides that drug products of the same company, whose formulation contains the same active ingredient, may be grouped in families sharing the same mark and adopting complements that distinguish the drug products.

The Resolution also mandates that the exclusion or replacement of the active ingredient demands the adoption of another mark for the medication. Thus, consider a family of analgesics whose active ingredient is "ibuprofen". If the manufacturer

replaces the "ibuprofen" by "dipyrone" in one of the products, the mark of that product would have to be changed, in a manner to adopt a different mark as opposed to the family.

The exceptions are the multivitamin, multimineral and multi amino acid products. In these cases, the mark of the family can be maintained, but the manufacturer should use complements indicating the target public of the product.

The Resolution also provides that, in case of families of drug products, the company should adopt complementary distinctive measures through packaging in order to promote distinction between the products. It is not clear, however, how distinctive the packages should be, since the use of look-alike trade dresses is an important commercial strategy when a family of drug products is concerned.

## CRITERIA FOR COMPLEMENTS OF NAMES OF DRUG PRODUCTS

Finally, Resolution RDC nº 59/2014 regulates the use of complements in pharmaceutical trademarks, pointing out that the complements must be used to distinguish certain medication from other medication registered by the same company, within the same family of products.

In respect to these complements, the Resolution provides that:

- ANVISA will not consider, for purposes of registration, the existence of exclusive rights over the name complement – this means that, in principle, the agency will presume that the name complement cannot be appropriated. Thus, if the company believes that the complement is distinctive and able to function as a mark, it should take judicial measures to avoid the inclusion of the complement in subsequent third party registrations;

- Using the same name complement with different meanings is prohibited;

- Pharmaceutical companies can, upon substantiated justification, use name complements to distinguish routes of administration, pharmaceutical forms, target publics, and absorption details of the drug products;

- Drug products presenting kinetics of different release, different pharmaceutical forms or different routes of administration within the same family must adopt name complements.

## CONCLUSION

ANVISA's new Resolution regulates several aspects related to the names of pharmaceutical products. Some changes are quite positive, such as the abolition of the "3-letters rule", a test which was severely criticized by the pharmaceutical industry and the entire trademark community.

On the other hand, the Resolution brings some specific provisions to the current regulatory scenario. This is extremely relevant because the rejection of the application can obstruct the launching and sale of the drug product in the market.

Pharmaceutical companies operating in Brazil, therefore, should be attentive to those rules and create an efficient interaction between their regulatory and intellectual property departments.

* * *

**Gustavo Piva de Andrade** is a lawyer, a registered industrial property agent and a partner at Dannemann Siemsen with 15 years of experience. His practice is focused on trademarks, trade dress, copyrights and unfair competition issues. Mr. Piva de Andrade counsels several multinational pharmaceutical companies in prosecution and infringement matters and litigates a wide range of IP and regulatory cases in federal and state courts. He has an LL.M in Intellectual Property Law by Franklin Pierce Law Center (USA).

gpa@dannemann.com.br



mail@dannemann.com.br
www.dannemann.com.br