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The Mexican General Health Law was reformed on June 11, 2009 to include an article 222 bis, which defined biotechnological drugs, and allowed for the approval of "biocomparables." The decree came into force on September 8, 2009, and the Ministry of Health had a 180-day period to issue all specific regulations pertaining to the approval of these biocomparables.

Even though the 180-day period expired on March 8, 2010, work on the project of regulations has continued, with input being provided by both the Mexican Association of Pharmaceutical Research (AMIIF) and the National Association of Drug Manufacturers (ANAFAM).

This past week, COFEPRIS (the Mexican regulatory authority) made the project of regulations available to the public, through the official website of the Federal Commission for Regulatory Improvement (COFEMER).

At this point, a period of 30 working days

has been given to any interested party that wishes to provide comments to this project through COFEMER's website, after which the project can be either published or further analyzed.

The main items in this project are:

- A definition of comparability tests between an innovator and a biocomparable drug.

- An indication that biocomparable drugs will use the same name for the active ingredient as the innovator.

- The Health law regulations currently contain a 3-year period *Roche-Bolar*-like research exemption (related to the possibility of submitting an application for a marketing authorization before patent expiration, with intent to launch after the date of expiry). This 3-year period is eliminated, and the submission can now be made at any time. The modification in the corresponding article will also be applicable to chemical drugs.

- The timelines that COFEPRIS will have for approval of both innovator and biocomparable drugs are established.

The first of these documents is an official communication from COFEMER to COFEPRIS (the authority which oversees approvals) referring to the regulatory impact that the provisions will have, which was made public on August 9, 2010. COFEMER is requesting, amongst other things, the following:

- A justification for the elimination of the 3-year period in the *Roche-Bolar*-like research exemption in order to verify compliance of provisions in the Industrial Property Law.

- Justification for each requirement to approve biocomparable drugs.

- Additional information on cost impacts that the new regulations will have on industry participants.

result in the authorization of drugs without full review of the applications by the corresponding authority, which might generate sanitary risks.

Source: Patents Doc, 2010.

- Additional information on reductions of public health expenditures derived from the regulations.

This communication has been delivered by COFEPRIS which will have to make the necessary justifications and adjustments to its proposal, before submitting anew to COFEMER. There is no specific deadline contemplated for this

purpose. After the project is revised, if modifications are made, a new 30-day period will be granted to the general public to provide comments.

The second document contains a review by the Mexican Association of Pharmaceutical Laboratories (AMELAF) with a proposal for modifications to the project of regulations. In this proposal, the main items are the following:

- Concerning the *Roche-Bolar* *Mexican Supreme Court Decides on Broad Interpretation of Linkage Regulations"). This specific proposal is very likely to be contended by AMIIF, and/or individual patent holders.*-like exemption, AMELAF is proposing to change the wording in order for linkage review by COFEPRIS to be made only in regards to the first *"molecule"* (active ingredient) patent, which would be applicable both to biotech and chemical drugs. This goes directly against the decision by the Mexican Supreme Court, which interpreted linkage regulations to include patents covering pharmaceutical formulations as well (*see* "

- AMELAF is also proposing to make most regulatory requirements for the approval of a biocomparable drug subject to the discretion of the Ministry of Health on a case by case basis. The current project contains mandatory pre-clinical and clinical trials, pharmacodinamics studies, immunity response studies in animals and *in vivo* studies. The proposal by AMELAF is to make all of these requirements applicable "if necessary."

Whereas this proposal could have some merit in order to avoid studies that would prove to be unnecessary for specific drugs, it should be allowed only if a correlating provision providing for regulatory exclusivity is passed, in order to maintain a balance between the innovators making the initial studies and subsequent market entrants. No such provision is contained in the project.

- Additionally, AMELAF is proposing that the term for COFEPRIS to approve a biotech drug be reduced from 235 to 180 working days, and that, if that term expires without a response, then the application is understood as granted. This last item is not likely to be approved, as it could