by Alejandro Torres

A draft of Mexican Official Standard NOM-257-SSA1-2013 that will affect the way the procedures for obtaining marketing authorisations for medicaments are performed, as well as renewal and modifications of those authorisations, is under review. Mexican Official Standards (NOM) aim to ensure compliance in terms of values, quantities and minimum or maximum characteristics in the design and production of consumer goods or services between corporations and/or individuals, especially paying attention to the public in general, and are mandatory. The draft NOM 257 refers to important topics for health regulations in Mexico such as follow-ons – biocomparables, clinical studies, pharmacovigilance and the linkage system. The relationship between NOM 257 and the linkage system in Mexico affects other IP rights, leading to comments and suggestions on the project.

Linkage system in Mexico

In Mexico, the linkage system for patents related to medicines was established by a modification issued on September 19 2003 to the Health Law Regulations and the Industrial Property Regulation, specifically by the inclusion of Articles 167 bis in the Health Law Regulations and 47 bis in the Industrial Property Regulations. The main purpose of the Linkage Regulation is to establish a link through coordinated rules between the regulatory agency in charge of granting marketing authorisations for medicines (COFEPRIS) and the Mexican Patent Office (IMPI), under the rationale of preventing issuance of marketing authorisations which may fall within the scope of granted patents for medicines, thereby giving certainty for both applicants and the title holder of medicine patents. According to what is established in these articles, there are obligations on those who participate (IMPI, COFEPRIS and the marketing authorisation applicant):

Obligations on IMPI

• To issue a list of patents for allopathic medicines (Linkage Gazette) twice a year.

• To provide information to COFEPRIS as to whether there is a violation of IP

rights.

Obligations on COFEPRIS

• Before granting a marketing authorisation to third parties other than the patent's title holder, to check the listed patents, first by compound and then by the list of patented products issued by IMPI in the *Linkage Gazette*, which is organised according to the active ingredient's generic name.

• To request information from IMPI. If COFEPRIS requests technical assistance, IMPI has 10 days to produce an opinion on the scope of the patent and whether the product for which market authorisation is sought falls within it.

• To prevent the applicant if necessary.

• To reject the marketing authorisation request if there is no proof of being the title holder or licensee of a patent which would be eventually violated.

• To keep dossiers confidential.

Obligations on the marketing authorisation applicant

• To indicate whether they own a patent or have a licence for an active ingredient.

• Alternatively, to declare under oath that their application does not violate patents listed in the *LinkageGazette* and observes patent law. It is believed that NOM 257 aims to standardise the filing of information by individuals for obtaining or renewing marketing authorisations for medicines. In general terms, it seeks to reduce the cost and administrative burden for individual integration and reduction of information to be reviewed and decided by the health authority/regulatory agency.

Similarly, the NOM looks to apply with international and Mexican standards, partially equivalent to these international standards: (a) European Commission,

NTA, Volume 2B-CTD, foreword and introduction, edition June 2006 and ICH M4: (b) Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use. Regarding the linkage system, the draft of NOM 257 has added requirements for applicants to the linkage system that already exists in Mexico for the following concepts:

• New records/new molecules (Articles 5.4.1.10 and 5.4.1.10.1).

• New registration/generic drugs (Articles 5.5.1.13 and 5.5.1.14, 5.5.1.15).

• New molecules/vaccines (Article 5.6.3.11).

• Blood products (Articles 5.7.1.12 and 5.7.1.12.1).

• Orphan drugs (Article 5.8.1.1.3.17).

• Biotechnological drugs (Article 5.12.2.1.1).

• Modification including by COMBOS (Article 6.18.12).

From the review of these articles, it seems that the requirements are harmonised with the linkage system, specifically to prove ownership or exclusive licence rights derived from patents that claim the drug that is the subject of an application. However there are differences in the wording in each of the points of the NOM 257

project, which do not allow the required homologation. Taking into account that there is a linkage system to prevent the granting of medical records in violation of the rights derived from a patent and taking into account that one of the purposes of NOM 257 is the harmonisation of the information to be submitted, it is well worth including the adoption of a uniform text in drafting the points mentioned, as a unique drug patent linkage. NOM 257 is available on the website of the Commission for Regulatory Improvement (COFEMER) which is a Mexican government agency responsible for the improvement of the existing regulation to promote economic competitiveness and reduce regulatory costs. We will follow closely the development of the approval process of this project and will provide information on developments.

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