Administrative Drug Submissions to be Excluded From the PM(NOC) Regulations?

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Health Canada recently released proposed revisions to its *Patented Medicines (Notice of Compliance) Regulations* guidance document that, if implemented, will exclude certain administrative drug submissions (e.g., where a licensee cross-references a licensor's drug submission) from the scope of section 5 of the *PM(NOC) Regulations*. Section 5 of the *Regulations* sets out requirements that a second person (typically a generic manufacturer) must comply with in submissions seeking a NOC for a drug that references another drug marketed in Canada by a first person (typically an innovator) and in respect of which patents have been listed on the Patent Register.

Presently, drug manufacturers who submit administrative drug submissions pursuant to a licensing agreement trigger section 5 of the *Regulations* such that the licensee must address any applicable listed patents upon filing its administrative drug submission. Under the proposed revisions, only the originating NDS or ANDS (i.e., the licensor's drug submission) will trigger section 5 of the *Regulations*. Thus, while an administrative drug submission that cross-references the licensor's drug submission pursuant to a licensing agreement will not re-trigger section 5 of the *Regulations*, a NOC will not issue to the licensee until the licensor's drug submission receives its NOC. If, however, a licensor or licensee files a supplement to its respective submission (e.g., seeking a NOC for a change in formulation, dosage form, or use of the medicinal ingredient) that references a first person's drug, the proposed amendment would require that any patents on the Patent Register in respect of the first person's drug listed prior to the date of filing of the supplement be addressed.

The exclusion of administrative drug submissions from the scope of section 5 of the *Regulations* should decrease administrative burden on licensees, as the need to re-address patents already considered by the licensor in its submission is likely redundant. In this regard, companies that develop private label drug products based on licensed products may particularly benefit from the proposed revisions.

Stakeholders have until October 17, 2011 to provide their comments to Health Canada on the proposed changes.

Click here to access the proposed guidance.