

# Torys on Food and Drug Regulatory

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## Data Protection for “Innovative Drugs” – Guidance Now Final

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On March 24, 2009, Health Canada released the final version of the guidance document titled “Data Protection under C.08.004.1 of the *Food and Drug Regulations*”<sup>1</sup> (the Guidance). The Guidance was first published in draft form on June 25, 2007, followed by a comment period during which stakeholders were encouraged to provide feedback. The Guidance is effective March 30, 2009.

The Guidance relates to the administration of section C.08.004.1 of the *Food and Drug Regulations* (the Regulations) and is applicable only to those drugs that have received a Notice of Compliance (NOC) on or after June 17, 2006.

Under section C.08.004.1 of the Regulations, “innovative drugs” that contain a medicinal ingredient not previously approved in a drug by Health Canada are entitled to an eight-year term of data protection. This term can be extended for an additional six months for pediatric population submissions. If a subsequent manufacturer seeks an NOC on the basis of a direct or indirect comparison with an innovative drug, the manufacturer (i) may not file its drug submission for six years;<sup>2</sup> and (ii) will not receive an NOC until eight years (or eight years and six months) from the date the NOC was issued for the innovative drug. The Guidance indicates that this prohibition will also apply to a new drug submission for a subsequent entry biologic where an NOC is sought on the basis of a comparison to an innovative drug.

The Office of Patented Medicines and Liaison (OPML) maintains the Register of Innovative Drugs<sup>3</sup> (the Register), which lists all drugs that are subject to the protections of section C.08.004.1. There are currently 68 listings on the Register.

If a manufacturer believes that a drug qualifies as an innovative drug, it may (i) include a statement in the cover letter accompanying the new drug submission and copy the OPML; (ii) submit supporting information in its new drug submission; or (iii) communicate directly with the OPML by letter, drawing attention to a pending submission. The OPML will prepare a preliminary assessment and notify the

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<sup>1</sup> This document can be found at [www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data\\_donnees\\_protection-eng.php#tphp](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php#tphp).

<sup>2</sup> Note that there is an exception for drug submissions filed under Canada's Access to Medicines Regime under C.08.004.1(7) of the *Food and Drug Regulations*.

<sup>3</sup> The Register of Innovative Drugs can be found at [www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg\\_innov\\_dr-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php).

manufacturer of the results in writing. If a dispute arises, the manufacturer may provide written representations within 30 days. The OPML will only provide a preliminary acceptance of the drug for inclusion on the Register before an NOC is issued, because the drug in question must remain the *first* to be approved with the specific medicinal ingredient.

The Guidance indicates that combination drugs of which at least one ingredient is an innovative drug will receive data protection until the expiry of the original data protection period of the single innovative drug. Combinations of previously approved medicinal ingredients are not eligible for an additional data protection period.

The release of the Guidance was in part delayed because of stakeholder concerns regarding the regulation of subsequent entry biologics after a guidance document on this topic was released in early 2008. The comments received by Health Canada relating to data protection and subsequent entry biologics were considered in drafting this final version of the Guidance. A revised draft guidance document on subsequent entry biologics was released by Health Canada on March 27, 2009. 