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Beware If You Compare: Data Protection May Stop Approval Of A New Drug Submission

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Sanofi-Aventis's ELOXATIN® had been sold in Canada since 1999 under the Special Access Program (SAP) of Health Canada, which allows for sale of a drug in exceptional cases prior to receiving regular marketing approval, i.e. prior to the issuance of a Notice of Compliance (NOC). The active ingredient is Oxaliplatin, an injectable medication for colorectal cancer chemotherapy and one of the best-selling cancer drugs in the world.

On October 27, 2006, Hospira filed a new drug submission (NDS) in Canada for Oxaliplatin. This was one month before Sanofi-Aventis filed their own NDS for ELOXATIN®.

Hospira's NDS encountered difficulties and was not approved during the usual time-frame of one to two years. Meanwhile, Sanofi-Aventis leapfrogged Hospira's application and was first to receive a NOC, in 2007. Because it was first to obtain marketing approval, it was granted Innovative Drug status and data protection, expiring on December 15, 2015. During that time, other applicants would not be allowed to refer to ELOXATIN®'s Innovative Drug data, including product monograph information or safety and efficacy data.

The data protection regime is established by the Food and Drug Regulations, more precisely section C.08.004.1. Usually, data protection cannot prevent issuance of a NOC to a sponsor that does not refer to a drug currently under data protection. Thus, in most cases where an independent NDS is filed, data protection cannot be invoked.

In this situation, Hospira corresponded with Health Canada for years before it finally qualified for a NOC in 2013. Hospira accomplished this by relying on new information related to Sanofi's ELOXATIN®, including its Canadian product monograph. Unfortunately for Hospira, this attempt to move their application forward is ultimately what stopped it in its tracks.

In the fall of 2013, Health Canada refused to issue a NOC to Hospira because it had made a comparison to ELOXATIN®, which was still under data protection.

Hospira applied to the Federal Court to overturn the decision. On November 6, 2015, the Federal

Court dismissed the case (Hospira Healthcare Corporation c. Canada (Health), 2015 FC 1205).

The Court concluded that Health Canada was correct in finding that data protection applied even if the comparison to ELOXATIN® occurred as a post-filing amendment to an independent NDS.

This decision demonstrates how cautious applicants must be when agreeing to make a direct or indirect comparison to a drug under data protection. Health Canada will not guide applicants through such aspects of the process, and so they may spend years breaking down a wooden door only to find a concrete wall on the other side.

Please contact Serge Shahinian for more details on these issues.