Sunsetting the brand:
Is this the best strategy when a product will lose exclusivity?

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First, let's define the "sunset the brand" strategy (also called the "do-nothing" strategy). It can be summarized as a suspension of marketing and sales activities prior to, or after, the date of patent expiration. This strategy is often pursued when the task of fighting against numerous generics becomes too overwhelming and the result is brand retention of only 5 to 10% of market share. Companies that deploy transactional strategies with payers, generics companies and/or pharmacies may, at best, retain an additional 10 to 15% market share at reduced margins. These require lots of effort with minimal financial reward for maintaining the life of a brand.

The reality of the marketplace has evolved significantly over the past two decades. Many of the drugs launched today are specialty products and/or biologics. Their profiles differ from the traditional small protein drugs in that biologics are composed of larger proteins, polysaccharides or nucleic acids that are complex molecules and not fully structurally characterized. Biologic and non-biologic specialty medicines are often prescribed by specialists and address the needs of smaller patient populations. Manufacturers of these medicines often fund support programs to assist patients during their treatment pathway. As such, the development, production, submission to the health authority and HTA agencies, and the patient support requirements to meet treatment standards may represent a challenge in terms of time and cost for manufacturers of biosimilar products or specialty product generics.

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This may explain in part why, for the period of July 2018 to August 2019, only 37% of the brands whose patents had expired have generic competition. Not surprisingly, most of the genericized products were small proteins. This also means that nearly 63% of products with expired patent protection are without generic competition (several generic submissions are currently under Health Canada review).

Companies are, however, ramping up their expertise and production capacity to develop and properly introduce specialty generic and/or biosimilar medicines. Although the road to success for these products remains challenging, efforts are being made by providers, regulators and payors to make it easier and faster. Success requires an agile go-to-market approach which is different from usual generic strategies and may include actions similar to those taken by the innovative industry.

One such example is the agreements carried out with Innomar Strategies as a preferred provider to develop patient support programs for the members of Biosimilars Canada. Additionally, generic companies are increasingly structured to deploy and adopt similar strategies as brand companies. It is common to find ex-brand-pharma executives moving to the generic sister division.

Keep in mind the following facts;

- The regulation in Canada allows for eight-year data protection from the date of issuance of the first notice of compliance for the innovative drug.
- Canada, in order to comply to its obligation under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA) must put in place an opportunity to apply to an additional two-year expanded patent protection under the Supplemental Protection Certificate system.
  - 30 products have seen their patent extended for another two years and, as of September 2019, another two were pending decision.
- The USMCA (United States-Mexico-Canada Agreement) will provide 10 years of data protection for biologic drugs (when/if it is ratified by all the countries involved).

These patent protection elements allow brand companies to gain additional time to optimize the return on investment for their products and to prepare for the inevitable – that one day, a generic competitor will enter the market and rapidly take market share. For innovative companies, procrastination is not an affordable strategy. Preparing for this event with a loss-of-exclusivity (LOE) strategy must happen well in advance. Creating a life cycle taskforce, using internal resources from regulatory, legal, market access, production, marketing and sales force to assess and prioritize potential strategies; is key to successful preparedness. The implementation of life cycle management, if it is well executed, should prevent early or unexpected generic entries until the decision is made to "sunset the brand."

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