New Drug Development Timeline

01

Securing Active Pharmaceutical Ingredients (API's) & Quality Control

- API are produced internally or sourced from international suppliers.
- Assess legal issues effecting availability and use of API in Canada.
- API tested for quality and consistency prior to formulation.
- Assess quality control and manufacturing practices of supplier.
- Assess supplier ability to guarantee stable supply of API.

02

Formula Development

- Originator product reverse engineered for composition of active and non-active ingredients.
- Data collected, analysis of originator product monograph.
- Various formulations of active and non-active ingredients.
- Formulations are tested against brand-name product.
- Develop quality control matrix for formulation integrated into manufacturing.

03

Manufacturing and Production Testing

- Formulations tested in manufacturing setting.
- Analysis of manufacturing complexity and requirements.
- Equipment designed and/or purchased for dedicated production line.
- Quality control matrix developed, tested for full manufacturing.
- Packaging designed, produced with dedicated quality control matrix for output.

04

Bioequivalence Studies And Clinical Trials

- Bioequivalency studies undertaken to measure the rate and the extent of absorption of generic drug. Results compared to originator drug.
- Comparative study submitted to Health Canada.
- Submissions include evidence of tests and clinical trials to measure potency, purity, and stability of new drug.
- Health Canada cannot approve a generic drug until all relevant intellectual property issues are addressed.

05

Regulatory and Legal Challenges

- Under Patented Medicines (Notice of Compliance) Regulations a generic manufacturer is required to serve Notice of Allegation on the brand-name manufacturer, claiming generic drug will not infringe any relevant patents.
- Brand-name manufacturer can apply for an order prohibiting Health Canada from approving generic drug. Using "automatic stay" brand-name manufacturer can prevent generic product from entering market for up to 24-months simply by alleging patent infringement.

06

Provincial / Territorial Drug Plan Listings

- Once Health Canada has issued a Notice of Compliance (NOC) and approved the drug for sale, it can be sold anywhere in Canada.
- To be reimbursed under provincial drug programs and obtain significant sales volumes, the generic drug must be listed on provincial drug benefit plans and be "interchangeable" with originator.
- Manufacturer must submit an application to pan-Canadian Pharmaceutical Alliance (pCPA) and each province/ territory. It can take up to a year to have the new generic drug listed in all provinces.

07

Patient Journey

- Patient Support Programs
- Access and Education

Th is can take **several years and millions of dollars** to complete