Generic drugs can be manufactured after the periods of exclusivity on the brand-name versions have ended.

Generic and brand-name drugs have identical active ingredients, and generic drugs must meet Health Canada's standards for bioequivalence.

The process of bringing a generic prescription medicine to Canadians is complex, requires sophisticated scientific and advanced manufacturing technologies, and can take several years and millions of dollars to complete.

BRINGING HIGH-QUALITY COST-SAVING GENERIC MEDICINES TO CANADIANS

CGPA
Making Patient Care Affordable

BRINGING HIGH-QUALITY, COST-SAVING GENERIC MEDICINES TO CANADIANS

RESEARCH AND DEVELOPMENT

01 SECURING ACTIVE PHARMACEUTICAL INGREDIENTS (API's)

- 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 DEVELOPING FORMULAS

- 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.

BRINGING HIGH-QUALITY, COST-SAVING GENERIC MEDICINES TO CANADIANS

CLINICAL TRIALS / FEDERAL APPROVALS / PROVINCIAL AND TERRITORIAL LISTINGS / PATIENT JOURNEY

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
- Education