

GENERIC PRESCRIPTION DRUG DEVELOPMENT

Rx

GENERIC MANUFACTURERS INVEST **THREE TO SIX YEARS** AND AN ESTIMATED **FOUR MILLION DOLLARS** TO BRING A NEW GENERIC DRUG TO MARKET.

FROM CONCEPT

TO MARKET

February, 2010

KEY CONSIDERATIONS ASSESSED BEFORE DECIDING TO DEVELOP A NEW GENERIC DRUG

MARKET SIZE

The single most important consideration is the size of the market and the number of competing manufacturers. What percentage of the market is captured by the brand-name drug? What growth opportunities are there in this category of drug? Will there be generic competitors marketing the same drug?

DEVELOPMENT AND APPROVAL COSTS

An assessment is made of the total cost associated with introducing a new generic drug. These costs include research and development resources, product testing, legal and litigation fees, and federal and provincial approval requirements. All of the costs are measured against the market size and opportunities for growth.

TIMING

The question of time is a key consideration. How long will it take to develop the drug and how long will it take to obtain Health Canada approval? How long to obtain a provincial drug plan listing? These timing considerations are measured against market demand forecasts, changing demographics and the forecast date that a generic product can legally enter the market.

SPECIALIZATION AND PRODUCT PORTFOLIO

A manufacturer will review their drug specialization and portfolio in order to identify any benefits from economies of scale in their production. If a manufacturer specializes in drugs of a certain therapeutic class or dosage forms (e.g. injectables, ointments, creams) the new drug might complement their production. Alternatively, a manufac-

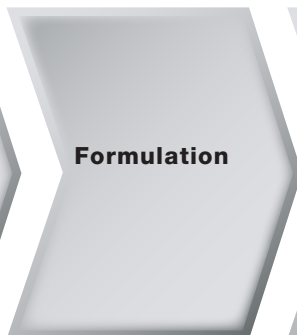
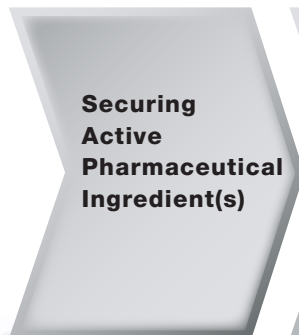
turer might want to expand their overall product portfolio to be a more attractive single source supplier to their customers.

LEGAL CHALLENGES

Bringing a generic drug to market typically includes legal challenges to a brand-name drug's various patents, which can be a costly and time consuming process. Contrary to popular belief, not all patents have merit or value. Brand-name companies routinely use strategic patenting to prolong their market monopolies and delay generic market entry.

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research & development



federal approvals



provincial listing



GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM **6 MONTHS TO A YEAR**,
WITH THE ESTIMATED
COST OF **\$250,000**

research & development

federal approvals

provincial listing

**Securing
Active
Pharmaceutical
Ingredient(s)**

Formulation

Testing,
Formulation,
Manufacturing
and Production

Bioequivalency
Clinical Trials

Legal
Challenges
and Costs

Provincial
Drug Plan
Listing

- The active pharmaceutical ingredients (API) are sourced from international suppliers or produced internally.
- The manufacturer conducts an assessment of any legal issues affecting the availability and use of the API in the Canadian market.
- The API must be tested for its quality and consistency prior to formulation.
- The supplier's production facilities need to be assessed for their quality control.
- The supplier's ability to guarantee a stable supply of the API is critical to the success of developing a generic drug.

FROM CONCEPT

TO MARKET

GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM **6 MONTHS TO A YEAR**,
WITH THE ESTIMATED
COST OF **\$250,000**



- The brand-name product is reverse engineered to determine the composition of its active pharmaceutical ingredients and non-active ingredients.
- Data is collected and reviewed. The product monograph of the brand-name drug is analyzed.
- Development of various formulations of the active and the non-active ingredients.
- Various formulations are laboratory tested against the brand-name drug.
- Development of a quality control matrix for formulation to be integrated into the manufacturing process.

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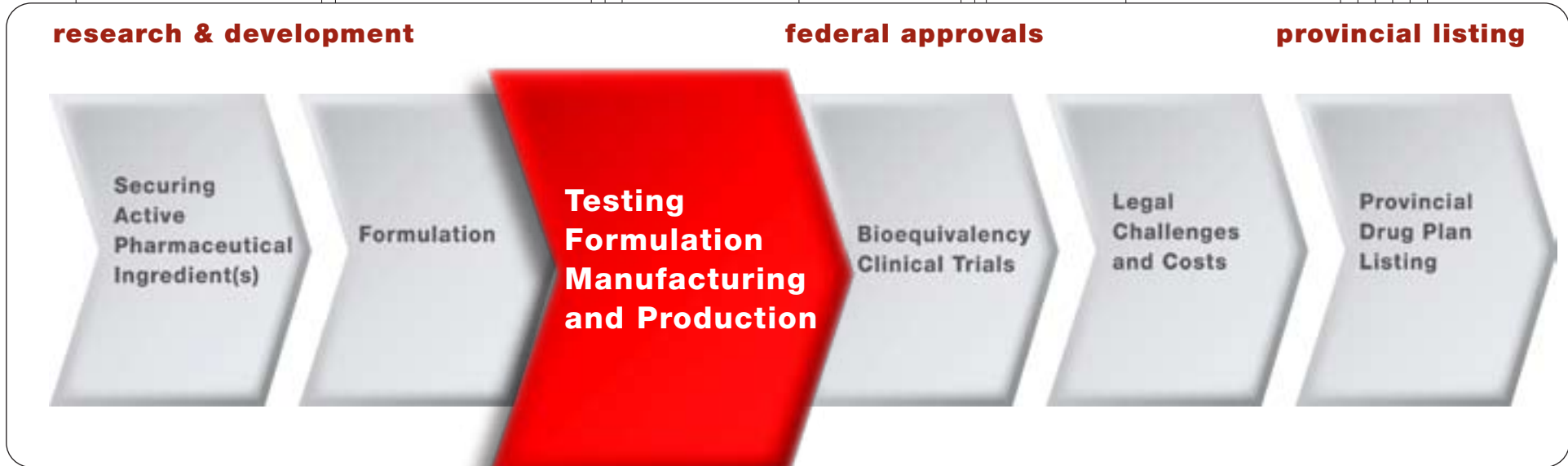
TO MARKET



GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM **9 MONTHS TO A YEAR**,
WITH THE ESTIMATED
COST OF **\$1,000,000**



- The generic drug formulations are further tested in the manufacturing setting.
- Complexity of drug manufacturing process determined.
- Manufacturing equipment designed and/or purchased for a dedicated production line.
- Production quality control matrix developed and tested in full manufacturing setting prior to federal approval.
- Packaging production is designed and quality control matrix developed to ensure consistency in product output.

FROM CONCEPT

TO MARKET



GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM 3 TO 6 MONTHS
WITH THE ESTIMATED
COST OF \$1,000,000



- Standard bioequivalency studies undertaken to measure the rate and extent of absorption of the generic drug. The results of the studies are compared to the same characteristics in the brand-name drug.
- The manufacturer files a submission with Health Canada, which contains data that compares the generic drug to the brand-name product.
- Submissions must contain sufficient data for Health Canada to assess the effectiveness of the generic drug to the brand-name drug. The submissions include the evidence of tests conducted to measure the potency, purity and stability of the new drug.
- Health Canada cannot approve a generic drug until any relevant legal issues are addressed.

FROM CONCEPT

TO MARKET

GENERIC PRESCRIPTION DRUG DEVELOPMENT



UP TO **TWO YEARS**
WITH THE ESTIMATED
COST OF **\$2,000,000**

research & development

federal approvals

provincial listing



- Generic Manufacturers are required, under the *Patent Medicine Notice of Compliance Regulations*, to serve a Notice of Allegation (NOA) on the brand-name manufacturer that claims that the generic product will not infringe any relevant patents.
- The brand-name manufacturer may apply to the court for an order prohibiting Health Canada from approving the generic drug. Using this “automatic stay,” the brand-name manufacturer can prevent a generic product from entering the market for to 24 months simply by alleging patent infringement.
- Health Canada cannot issue its approval to the generic - a “*Notice of Compliance*” (NOC) - until two years have elapsed or the court application has been dismissed.
- Being granted market authorization by Health Canada is not the end of potential legal issues for the generic product. The brand-name manufacturer may also initiate a separate patent lawsuit under the *Patent Act* as a threat to the marketing of the generic drug. The generic might succeed under the regulations, market the drug, and then be sued by the brand-name company for patent infringement. This relatively new problem of dual litigation is a major issue for generic manufacturers, which increases the legal cost and the level of uncertainty.

FROM CONCEPT

TO MARKET

GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM **3 MONTHS TO A YEAR**
WITH THE ESTIMATED
COST OF **\$250,000 - \$500,000**



- Once the generic drug has received Health Canada approval, it can be sold anywhere in Canada.
- To be reimbursed under the provincial drug programs and obtain significant sales volumes, the generic drug must be listed on provincial drug benefit plan formularies.
- The generic drug manufacturer must submit a separate application to each province and await response. It can take up to one full year to have the new drug listed in all the provinces.

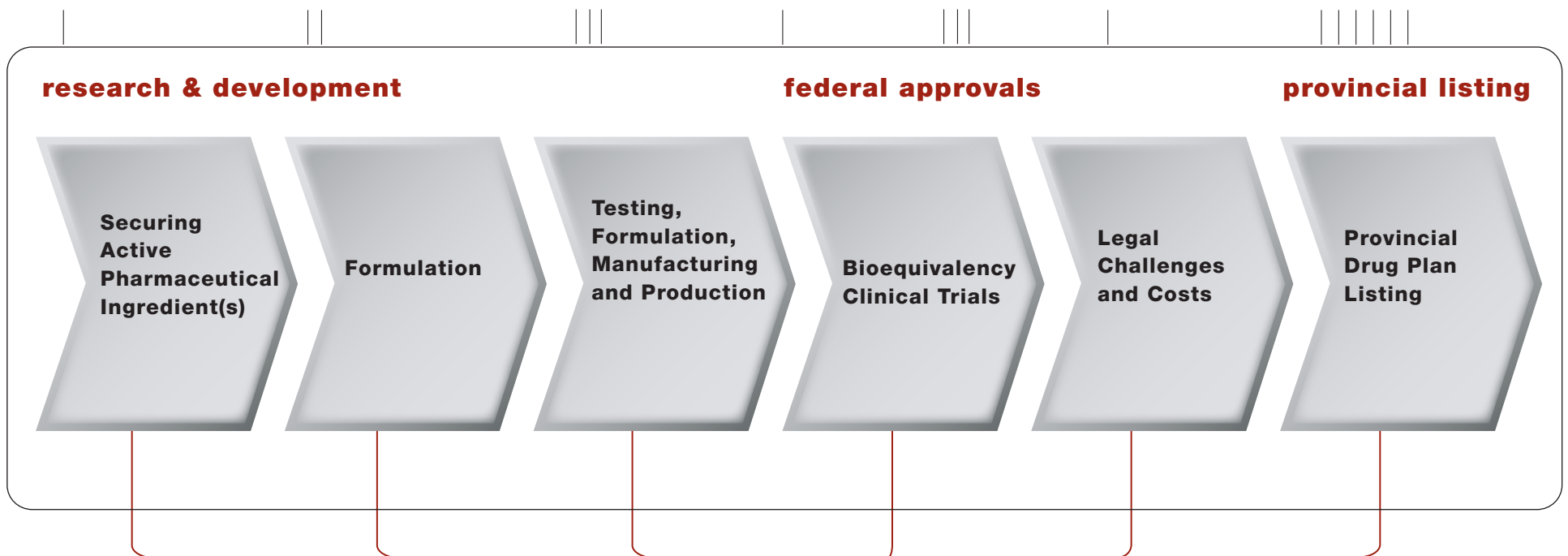
FROM CONCEPT

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GENERIC PRESCRIPTION DRUG DEVELOPMENT



FROM **THREE TO SIX YEARS**, WITH
AN ESTIMATED COST OF **FOUR**
MILLION DOLLARS.



OVERALL COSTS

- When a manufacturer decides to produce and market a new generic drug, the manufacturer typically requires up to six years to bring the new product to market.
- At each stage of the development the manufacturer invests heavily in research, development and human resources.
- It can take up to six years before a manufacturer is able to recover any of its R&D and capital investments, let alone earn a return on the investment.
- Generic Manufacturers currently face a great deal of uncertainty, which poses a significant challenge in making sound business decisions.

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