Biosimilars in Canada: What Does the Future Hold?

Drug Pricing in Canada
November 15-16, 2016

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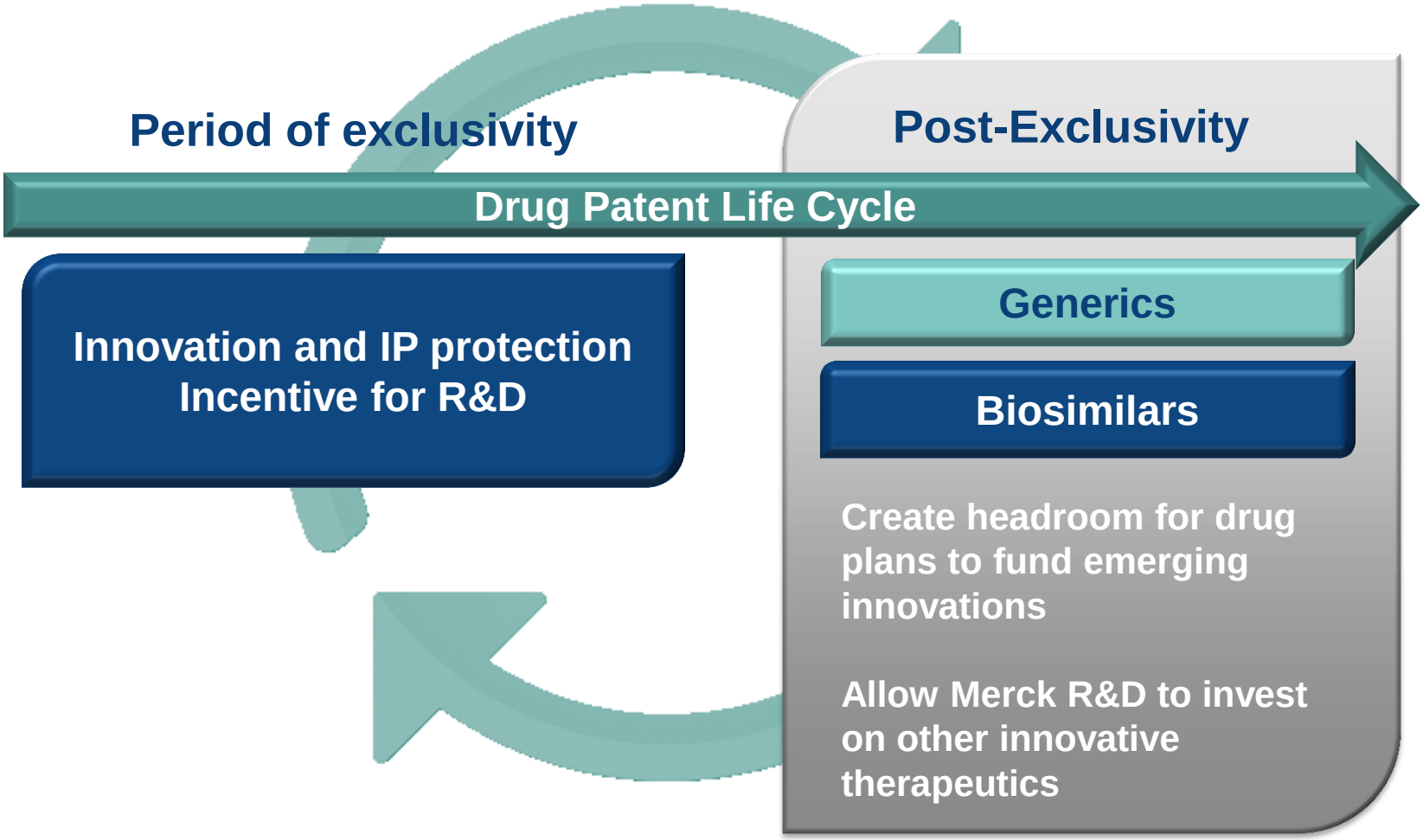
The Innovation Cycle: Supporting Innovation & Sustainability



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Biosimilars in Development and Status in Canada

A 'Subsequent Entry Biologic' is a biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug.[1]

Biologics with Biosimilars in Development[2]

Immunology	Oncology	Diabetes	Ophtalmology
Adalimumab (Humira*) Etanercept (Enbrel*) Infliximab (Remicade*) Rituximab (Rituxan*)	Bevacizumab (Avastin*) Trastuzumab (Herceptin*) Pegfilgrastim (Neulasta*) Epoetin Alpha (Epogen*) Darbepoetin Alpha (Aranesp*) Filgrastim (Neupogen*)	Insulin Glargine (Lantus*)	Ranibizumab (Lucentis*)

Biosimilars Approved in Canada

Biologic	Biosimilar	NOC	Reimbursed
Somatropin (Genotropin*)	**Omnitrope***	04/2009	Yes
Infliximab (Remicade*)	**Inflectra***	01/2014	Yes
Insulin Glargine (Lantus*)	**Basaglar***	09/2015	No (PCPA)
Filgrastim (Neupogen*)	**Grastofil***	12/2015	No (PCPA)
Etanercept (Enbrel*)	**Brenzys***	09/2016	No

1. Health Canada: Questions & answers to accompany the final guidance for sponsors: information and submission requirements for SEBs.
2. CADTH Environmental Scan: SEBs Emerging Trends in Regulatory and Health Technology Aseesment Frameworks, Issue 43, January 2014

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Why Biosimilars Should be Treated Differently than Generics?

Small molecule

- Proof of quality (identical chemical structure)
- No substantial clinical data required: bioequivalence
- Development cost: $USD 1 - $5 M[1]
- Development time: 2 to 3 years[1]

Generics

Biological medicine

- Proof of quality and purity, made from same building blocks
- Clinical data required to show high similarity in pharmacokinetics, efficacy and safety
- Development cost: > USD$100 M[1]
- Development time: 5 years[1]
- Significant investment in patient support services and education

Biosimilars

1. Henry G. Grabowski, Rahul Guha and Maria Salgado, Regulatory And Cost Barriers Are Likely To Limit Biosimilar Development And Expected Savings In The Near Future, Health Affairs, 33, no.6 (2014):1048-1057

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Current State of Acceptance of Biosimilars

- Patients and physicians generally agree that biosimilars have a role to play in providing additional, lower cost treatment options for patients[1]
- Physicians highlight a significant need for evidence-based education about biosimilars.[2]
- Physicians and patients position biosimilars as suitable treatment options for naïve/ new patients but do not support forced switching of stable patients.
- Patients wish to be informed and involved in decision-making concerning biosimilars.[3]
- Payers anticipate biosimilars will be a strategy to reduce specialty drug prices and most believe the category represents a compelling business opportunity.[4]

1. CAPA (Aug 2014), The Arthritis Society (Nov 2015), GSI (May 2016)
2. Cohen H et al., Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians, Advances in Therapy, Oct 2016
3. Peyrin-Birouleta L et al., Patient Perspectives on Biosimilars: A Survey by the European Federation of Crohn's and Ulcerative Colitis Associations, Journal of Crohn's and Colitis Advance Access, August 2016
4. GABI Online: Payers in US view biosimilars as a lower-cost branded option, Posted 15/04/2016

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Is Canada Missing Out on the Biosimilar Opportunity?

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

MARKET INTELLIGENCE

BIOLOGIC RESPONSE MODIFIER AGENTS, 2015

- While there has been a substantial uptake in the biosimilars for infliximab in many OECD countries, the uptake in Canada has been low (0.2% based on private drug plan data).
- Competition from Inflectra, a biosimilar that costs nearly half the price of Remicade, has been much lower in Canada than in other OECD countries. If the use of the biosimilar for Remicade in Canada had mirrored the median OECD use in 2015 (10.1%), it would have translated into $41.7 million reduction in drug expenditures.
- If the biosimilar uptake in Canada was in line with that of Norway, the country with the lowest biosimilar price and one of the highest uptakes at 67.8%, the cost implications would be substantial: a reduction of $280.1 million in drug expenditures.

Source: Patented Medicine Prices Review Board, Market Intelligence report, Biologic Response Modifier Agents, 2015

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The Future State of Biosimilars

A sustainable biosimilars market which is attractive and delivers continuing benefits to all concerned stakeholder groups, physicians, payers, patients, and industry, in both the short and long term.

- Introduction of several biosimilars across therapeutic fields to expand savings opportunities (all)
- Opportunities to treat more patients with appropriate therapies (physicians)
- Cost savings and financial sustainability of healthcare systems (payers)
- Improved access to medicines (patients)
- Reasonable return on investment with the continued attractiveness of R&D investment in new medicines development (industry).

Factors Supporting a Sustainable European Biosimilar Medicines Market, A study undertaken by GfK Market Access on behalf of the European Biosimilars Group (EBG), a sector group of the EGA, about the future sustainability of the biosimilar medicines market, Sept 2014

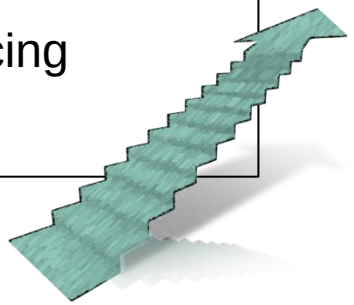
What is Needed to Establish a Viable Biosimilar Market that Delivers Sustainable Benefits to all Stakeholders?

BARRIERS

- Lack of knowledge and confidence towards biosimilars
- Suboptimal reimbursement policies
- Uncertainty about interchangeability
- Innovators' response

OPPORTUNITIES

- Evidence based education
- Implementation of policies and incentives to support biosimilar uptake
- Development of clinical experience and real world evidence
- Patient support
- Sustainable pricing



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