Towards an Alberta approach for biosimilar reimbursement

Summary report of the IHE Biosimilars Forum

October 6, 2016

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The Institute of Health Economics (IHE) is an independent, not-for-profit organization that performs research in health economics, synthesizes evidence in health technology assessment to assist policy making, and serves as a neutral broker to convene stakeholders from the public and private sectors to collaborate and solve key challenges in the health system.

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Declared Competing Interest of Authors

Competing interest is considered to be financial interest or non-financial interest, either direct or indirect, that would affect the research contained in this report or create a situation in which a person's judgement could be unduly influenced by a secondary interest, such as personal advancement.

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Executive Summary

Introduction

The Institute of Health Economics (IHE) Biosimilars Forum was held on October 6, 2016 in Edmonton to discuss an Alberta approach to biosimilar reimbursement. The purpose of this event was to gather key stakeholders from the public and private sectors, as well as clinicians, academics, and patient and provider associations, in order to inform Alberta biosimilar reimbursement policy by sharing international experiences in this area, and the perspectives of key individuals and organizations.

The format for the day was a number of presentations from invited international speakers, each followed by audience table reflection to identify key takeaways and implications for Alberta, and then a panel discussion.

A Multi-Factorial Approach

Reflecting on thought-provoking presentations on European approaches and outcomes observed, the discussion identified that the achievement of biosimilar policy objectives in Alberta will likely only occur through a multi-factorial approach that encompasses a number of elements beyond mechanisms to secure the lowest priced biologic. The group identified that we will achieve biosimilar objectives through the combination of:

- effective procurement strategies to capture value;
- clinical efficacy, safety and economic evidence development, and communication;
- education and experience;
- appropriate and enabling incentives to encourage utilization; and,
- active and sustained competition.

Procurement Strategy to Capture Value

A number of policy considerations to guide strategy emerged from the discussion. The group highlighted that Alberta procurement strategy to capture value should:

- differentiate first on the basis of best judgement regarding available clinical evidence, and then on price or other measures of value;
- assess value by more than just price and include other important considerations such as value-added services, quality, and reliability of supply;
- align with interest in prospectively monitoring experience and outcomes, and not create conditions where this is not possible or practical;
- support long-term attractiveness of the market for manufacturers (of originator and biosimilar products) when defining which manufacturers may compete, the number of products provided market access for all or some segments of patients or indications, as well as the longevity of reimbursement decisions; and,
- address the sustainability, quality, and consistency of the supporting infrastructure currently available for many biologic treatments (e.g., infusion clinics, patient support programs), as

well as practical and logistical considerations related to these elements in the event of public insurance biologic reimbursement differing from that of private insurance.

The group further identified that as Alberta develops reimbursement policy, there is a need to ensure that it is designed to be sustainable over time, and to anticipate new originator biologics entering the market, the potential for a significant number of biosimilars to enter, as well as a dynamic biologic agent context in terms of indications and place in therapy. Given a pan-Canadian approach for pharmaceutical economic evaluation and negotiation, the group noted that Alberta will not develop reimbursement policy in isolation from other provinces. The group identified a leadership opportunity for Alberta to work within the pan-Canadian framework to advance biosimilar reimbursement policy at a national level.

Evidence Development and Performance Monitoring

The discussion identified that an important step to get started with biosimilar reimbursement policy in Alberta is to identify where best judgement suggests we currently have enough data that biosimilar products are safe and efficacious with no clinically meaningful differences from comparator reference drugs, and where we do not. From this starting point, for biosimilars to play an increasing and evolving role in the health system, the group discussed a need to continue to build the clinical evidence base for them, including real world evidence development, in order to define what *similarity*, *non-equivalence*, and *non-identical* really mean, and to provide confidence and comfort for patients, providers, payers, and other stakeholders.

The group observed that this forum was a good start to develop key performance indicators (KPIs) that monitor and report on Alberta's biosimilar experience and outcomes relative to policy objectives, but additional work here is required. Directionally, the group highlighted that safety as well as clinical and economic outcome KPIs are the most important, comparing the performance of biosimilars relative to the performance of originators. Additionally, it was noted that KPIs to demonstrate if utilization of therapies changes as anticipated with the introduction of biosimilars are important, including measures of the appropriateness of any increased utilization of biologics consequent to change in place of therapy given improved value for money. Finally, it was reinforced by many participants that it is critical to develop KPIs that broadly track data from the patient perspective, including the patient experience, patient-reported outcomes, quality of life, and economic measures such as productivity and absenteeism.

Education and Experience

The group recognized that patients and providers will need to be aligned with biosimilar reimbursement policy in order for Alberta to achieve policy objectives, including utilization of biosimilars as intended. The group highlighted the importance of education appropriate to the Alberta culture and the use of clinical champions to encourage first-hand experience and to share current evidence and the objectives we are trying to achieve with reimbursement policy, along with the processes and mechanisms established or planned to capture data and answer questions over time.

Value-Added Enablers

The discussion concluded that many of the incentives utilized in the European context are not applicable to the organization or culture of health care in Alberta. Incentives were reframed for the Alberta context in terms of important value-added infrastructure and investments that are required to enable change in practice. These enablers include both clinic and patient supports, education,

experience programs, and infrastructure and investments in product delivery and patient support programs. It was noted that we might use current infrastructure and investments as a benchmark to articulate expectations for biosimilar product entry. Further, it was noted that there is a need to understand how transitions between value-added enabling elements can be effectively managed following biosimilar introduction, for example patients transitioning between different manufacturer support programs. Finally, the group identified a need to understand practical and logistical considerations related to enabling elements in the event of public insurance biologic reimbursement differing from that of private insurance, and for those that migrate between different public drug plan jurisdictions.

Active and Sustained Competition

The group recognized that an active and sustained competitive market is required in order for Alberta to benefit from new options and opportunities introduced by biosimilars over the long term. The group noted that Alberta will need to consider the:

- inclusiveness of competitive processes with regards to both originator and biosimilars;
- methodology for how value is measured;
- number of products provided market access for all or some segments of patients or indications; and,
- longevity of reimbursement decisions.

The discussion noted that the challenge in order to increase value for money in a post-patent biologics world is to structure competition to be as fair and inclusive of both originator and biosimilar manufacturers as possible, yet support long-term interest by biosimilar manufacturers to continue to develop new options given an ability to earn a return on their investment, and to identify how to measure value in a manner that includes price, but also other important value drivers such as services provided, quality, and reliability.

Summary of Next Steps

The following summarizes a number of next steps that were identified for consideration at the IHE Biosimilars Forum:

1. Identification of a process and leadership for continued stakeholder engagement, including a mechanism to engage patients.
2. Consideration of a leadership role for Alberta to stimulate a pan-Canadian dialogue and identify how the provinces might collaborate for a consistent, responsive, and transparent pan-Canadian approach to biosimilar reimbursement policy.
3. Determination of a biosimilars "entry package" that includes a multi-factorial approach, and articulates stakeholder roles and contributions, including expectations of biosimilar manufacturers wishing to enter the Alberta market.
4. Identification of the clinical efficacy, safety, and economic questions we wish to answer over time that will demonstrate where biosimilars can play a useful role, and where they should be avoided.
5. Establishment of a mechanism (e.g., patient registries) and leadership/structure to prospectively track utilization and outcomes achieved, importantly including those reported by and valuable to patients.

6. Development of Key Performance Indicators and a mechanism to regularly report on them relative to policy objectives.
7. Development of culturally appropriate educational material for patients and providers, as well as clinical champions that share current evidence for biosimilars and the objectives we are trying to achieve with reimbursement policy, along with the processes and mechanisms established or planned to capture data and answer questions over time.
8. Development of an inventory and valuation of current provincial infrastructure and originator manufacturer investments for biologics delivery and patient and other supports, as well as an understanding of how transitions between value-added enabling elements can be effectively managed with biosimilar introduction, including issues related to differences between public and private insurance biologic reimbursement.
9. Identify methodologies to measure and evaluate value, as well as appropriate competition models (including any role for government) that enable an active and sustained competitive market for post-patent biologics.

Concluding Comments

The IHE Biosimilars Forum represented a good start in terms of a broad group of stakeholders coming together to discuss complex and challenging issues related to biosimilar reimbursement. A rich and productive discussion took place, with stakeholders from different perspectives engaging and sharing experience and considerations to inform an Alberta approach to reimbursement. However, there is much more to do to articulate, implement, and monitor a thoughtful and sustainable Alberta approach. The level of interest and engagement at this event suggests that the stakeholder community is prepared and willing to continuously be engaged to implement some of the next steps emerging from this event, and to participate in similar future forums to evolve the discussion and support Alberta to define and achieve biosimilar reimbursement policy objectives.

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1. Introduction

1.1 IHE Biosimilars Forum Overview

This report follows from the Institute of Health Economics (IHE) Biosimilars Forum that was held on October 6, 2016 in Edmonton. This is the second IHE Forum on biosimilars that has been conducted, with the first held on May 29, 2014. More information on this first event can be found at: *http://www.ihe.ca/research-programs/knowledge-transfer-dissemination/conferences/biologics/bios-about*.

The purpose of this second event was to gather key stakeholders from the public and private sectors, as well as clinicians, academics, and patient and provider associations, in order to inform Alberta biosimilar reimbursement policy by sharing international experiences in this area, and the perspectives of key individuals and organizations.

A total of 63 individuals participated in the event, as well as two speakers and four additional panelists. Please see Appendix 1 for a copy of the program, which includes the agenda and biographies of the speakers and panelist; for a list of participants, see Appendix 2.

The format for the day was a number of presentations from invited international speakers, each followed by audience table reflection to identify key takeaways and implications for Alberta, and then a panel discussion. Participants were assigned seating to ensure each table reflected individuals from various perspectives (government, academia, clinicians, patient and provider associations, and originator and biosimilar industry).

1.2 Objective

The objective of the forum was to inform Alberta biosimilar reimbursement policy by sharing international experience in this area, and the perspectives of key stakeholders. As noted below, the forum was organized into three sessions in order to structure the presentations and discussion.

Session 1: International Experiences

- Introduction & welcome, opening video (*http://www.badgut.org/biosimilars*): *Dr. Richard Fedorak*
- The International Biosimilars Experience – Lessons for Alberta: *Mr. Murray Aitken, Executive Director, QuintilesIMS Institute*
- Table reflection on international experiences
- Panel discussion on international experiences

Session 2: Principles & Policy Options

- Towards Defining an Alberta Approach – Guiding Principles & Policy Options: *Dr. Asbjørn Mack, Chief Negotiator Pharmaceuticals, LIS, Norway*
- Table reflection on principles & policy options
- Panel discussion on principles & policy options

Session 3: Striking the Right Balance

- Panel discussion on Striking the Right Balance – Key Performance Indicators, Engagement, and Targets

2. Summary of Presentations

The following provides a summary of the two keynote presentations. Videos of each presentation and accompanying slides prepared by the invited speakers can be found at: *http://www.ihe.ca/research-programs/knowledge-transfer-dissemination/roundtables/ihebf/ihebf-pres*.

2.1 The International Biosimilars Experience – Lessons for Alberta

Mr. Murray Aitken, Executive Director, QuintilesIMS Institute

Biologics are increasing in terms of their role in patient care, and are consuming a growing share of overall drug spending. Innovation is anticipated to extend the role of biologics, as there are many new products in company research and development pipelines, including in areas where biologics have not previously had a significant role (e.g., cardiovascular, respiratory, pain, migraine). By 2020, $400 billion is globally forecasted to be spent on biologics of all type, with an estimated $6.0 billion spent in Canada.

There are a large number of manufacturers pursuing significant pipelines of biosimilars, including a mix of large global companies and smaller organizations, with many concurrently involved in the originator and biosimilar space. Interest in biosimilars is driven by a loss of exclusivity of key biologic products. It is important to note that the biosimilars area is a moving target as we think about reimbursement policy, and there is a need to develop policy that is sustainable in context of a dynamic biologics market with new innovations emerging, and many biosimilars anticipated.

Biosimilars have been on the market in Europe for over a decade. Different health systems have approached biosimilars differently from a reimbursement perspective. Biosimilar uptake and utilization has varied considerably, due to:

- differences in health system culture related to small molecule generics relative to brands;
- varying degrees of biologics usage, with wide variation in per capita availability and utilization of biologics across countries and across therapeutic categories and indications;
- strength of clinical evidence required to drive a behavioural change, and strength and role of clinical champions including scope of their influence (national, regional, local);
- organization of health care including the level of decision-making and fragmentation;
- organization of purchasing including linkage to clinicians and budget-holders; and,
- culture of "incentives" to the prescriber, both positive and negative.

There are four elements to consider when developing biosimilar reimbursement policy: pricing, procurement, prescribing, and dispensing. These considerations are likely very dynamic and will need to evolve as the experience, usage, and availability of biosimilars evolves. From the outset, building in mechanisms for flexibility is important.

Pricing considerations relate to the price of the originator after biosimilar entry, the price of the biosimilar relative to the initial originator price, and pricing mechanisms applied to biologics in a post-patent market (e.g., mandated reductions, "free pricing" with expected reductions during negotiations, or international or local reference pricing for originators and biosimilars). Many European countries have not explicitly acknowledged that biosimilars are identical to the originators, but from a pricing perspective for the purpose of reimbursement have treated them as the same.

Procurement considerations relate to how tenders are used to negotiate price and volume arrangements with manufacturers, as well as the scope (i.e., national/regional/hospital). European tendering involving a competitive process including both originator and biosimilar has varied according to position on interchangeability (e.g., United Kingdom tendering for EPO where originator and biosimilar are treated as if interchangeable) and patient segment (e.g., naive versus existing).

Prescribing considerations relate to guidance regarding when it is appropriate for a biosimilar to be used (e.g., naive patients or for those on stable therapy, either the originator or another biosimilar), and clinical thought leader-driven education programs to encourage their application. Additionally, incentives, both positive (e.g., gainsharing for hospitals) or punitive (e.g., quotas with penalty to the prescribing entity if not met) are also factors to consider to stimulate an openness to alternatives to the originator.

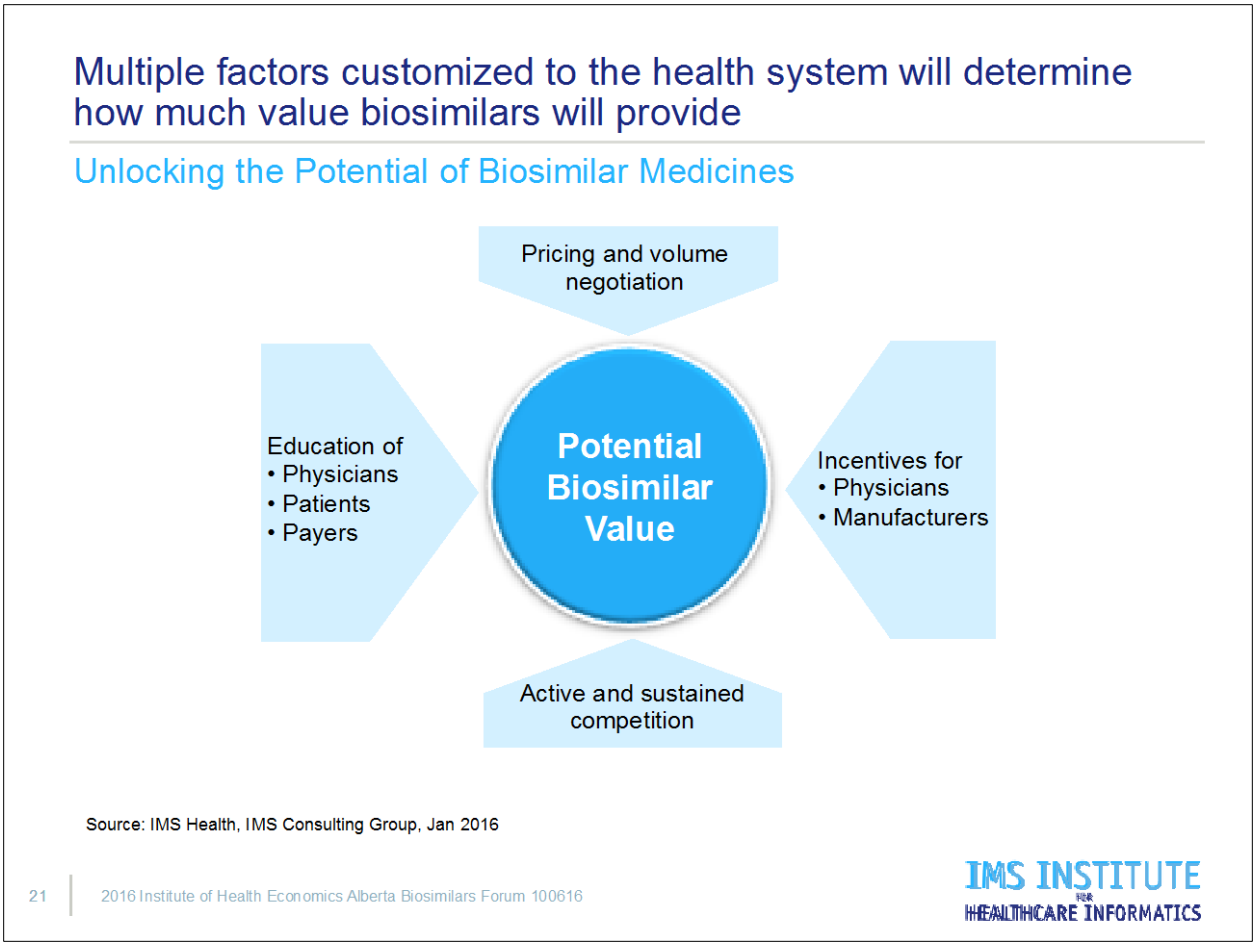
Dispensing considerations include automatic substitution at the pharmacy level of a different biologic than the one prescribed. This approach is not observed in any health system at present.

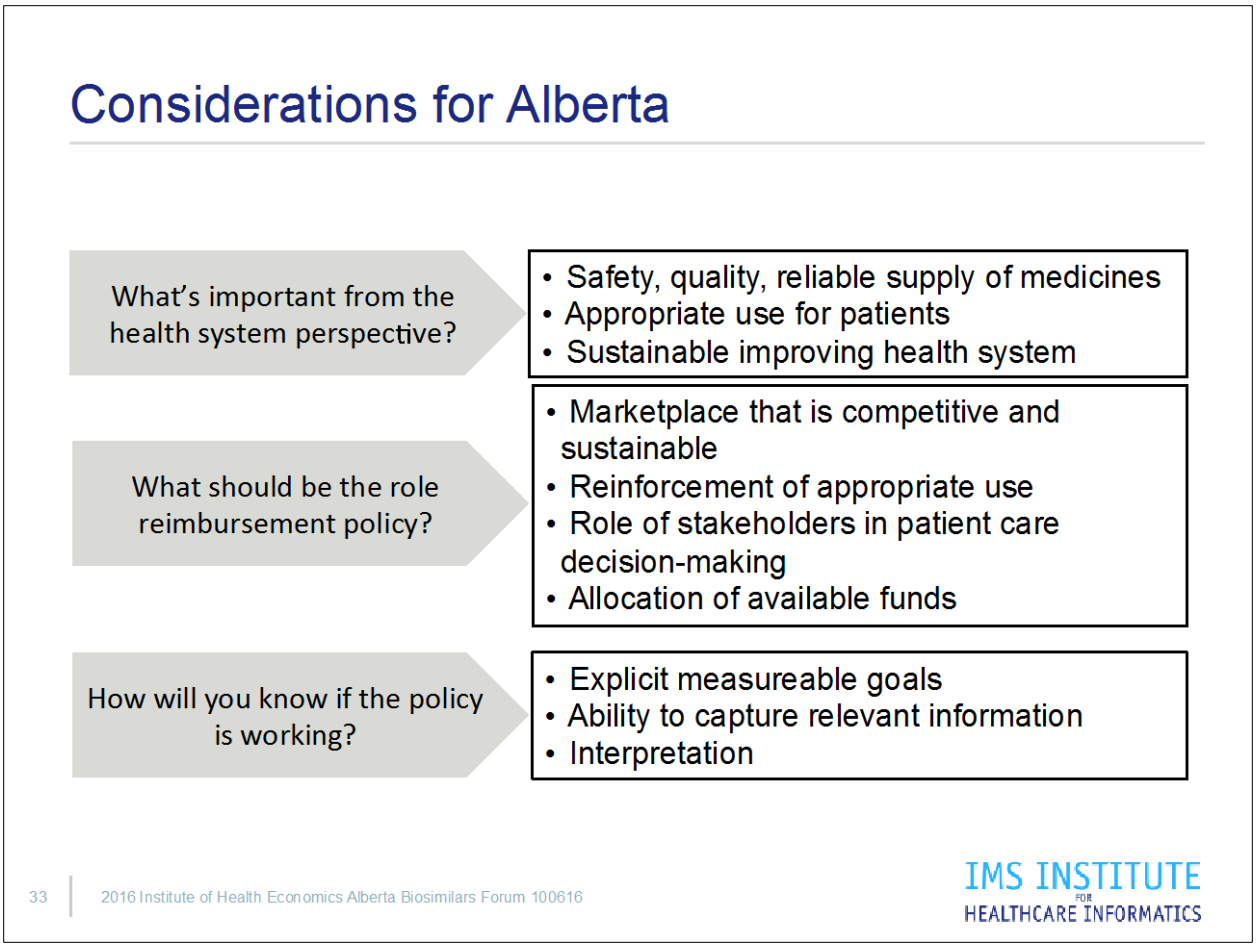
QuintilesIMS has prepared a set of indicators to monitor the impact of biosimilars in European markets (using invoice pricing not reflective of any discounts), and as a result of this work have identified five key observations:

1. **Competition from biosimilars drives down price for both biosimilar and originator (reference) product, but also pricing in the whole product class.** Price (per treatment day) declines are observed to be more significant when there are more biosimilars, and when biosimilars have been on the market for a longer time. Price reductions vary by European country, with those with the largest reduction in the range of 50 to 70%. These price reduction observations relate to categories that represent small markets (e.g., EPO, GSF, HGH), and extrapolation of these observations as an expectation for large markets where biosimilars are only recently available (e.g., anti-TNF and oncology) may not be appropriate.
2. **The correlation between biosimilar market share and price reduction is weak.** It is therefore not all about price but rather other factors, as noted above.
3. **Competition from biosimilars can influence the behaviour of the originator (and create a dynamic market).** Originators have been observed to reduce their price in order to maintain share, launch innovative long-acting/pegylated products without a price premium compared to the corresponding short-acting products (and change the treatment paradigm and, therefore, usage pattern), and launch biosimilar products of their own.
4. **Lower price has the most impact on utilization in countries with the lowest initial utilization.** Expanded usage of biologics has been observed when biosimilars at lower prices have become available, which may be driven by affordability, improved economic conditions, or changes to disease prevalence and diagnosis.
5. **There is variation between classes and products.** This is dependent on the length of treatment, frequency and mode of administration, differences in approved indications for agents within the class, innovations within the class, and strength of clinical evidence and clinical champions.

Going forward for Alberta, for biosimilars to bring value to the health system and provide a safe and effective treatment option that can come at a lower cost, there has to be alignment around four factors:

1. Education of physicians, patient, and payers
2. Effective negotiation of price and volume
3. Balanced incentives for prescribers and manufacturers (for the latter to want to enter the market and compete)
4. Active and sustained competition to ensure more than one manufacturer competing in the market with incentive to continue to participate over time





2.2 Towards Defining an Alberta Approach – Guiding Principles & Policy Options

Dr. Asbjørn Mack, Chief Negotiator Pharmaceuticals, LIS Norway

Norway has 5.2 million people and a publicly financed health system. Although not a member of the European Union, Norway follows European Medicines Agency decision-making. Amongst the Organisation for Economic Co-operation and Development (OECD) countries, Norway has one of the lowest percentages of total health expenditures spent on pharmaceuticals. Norway has pharmaceutical price controls, with maximum pricing based on a basket of nine European countries, where prices must not be higher than the average of the three lowest prices.

Norway has had biosimilars on the market since 2006, and they were first introduced without any guiding principles. There was significant negative information from industry regarding biosimilar safety, with no information provided by other sources, including the Regional Health Authorities. As a consequence, there was little utilization. In 2010, Norway tried an automatic switch initiative in pharmacies (like small molecule generics) for a biosimilar; however, a legal ruling stopped the initiative. Other general communication approaches requesting that physicians prescribe lower price biosimilars were ineffective.

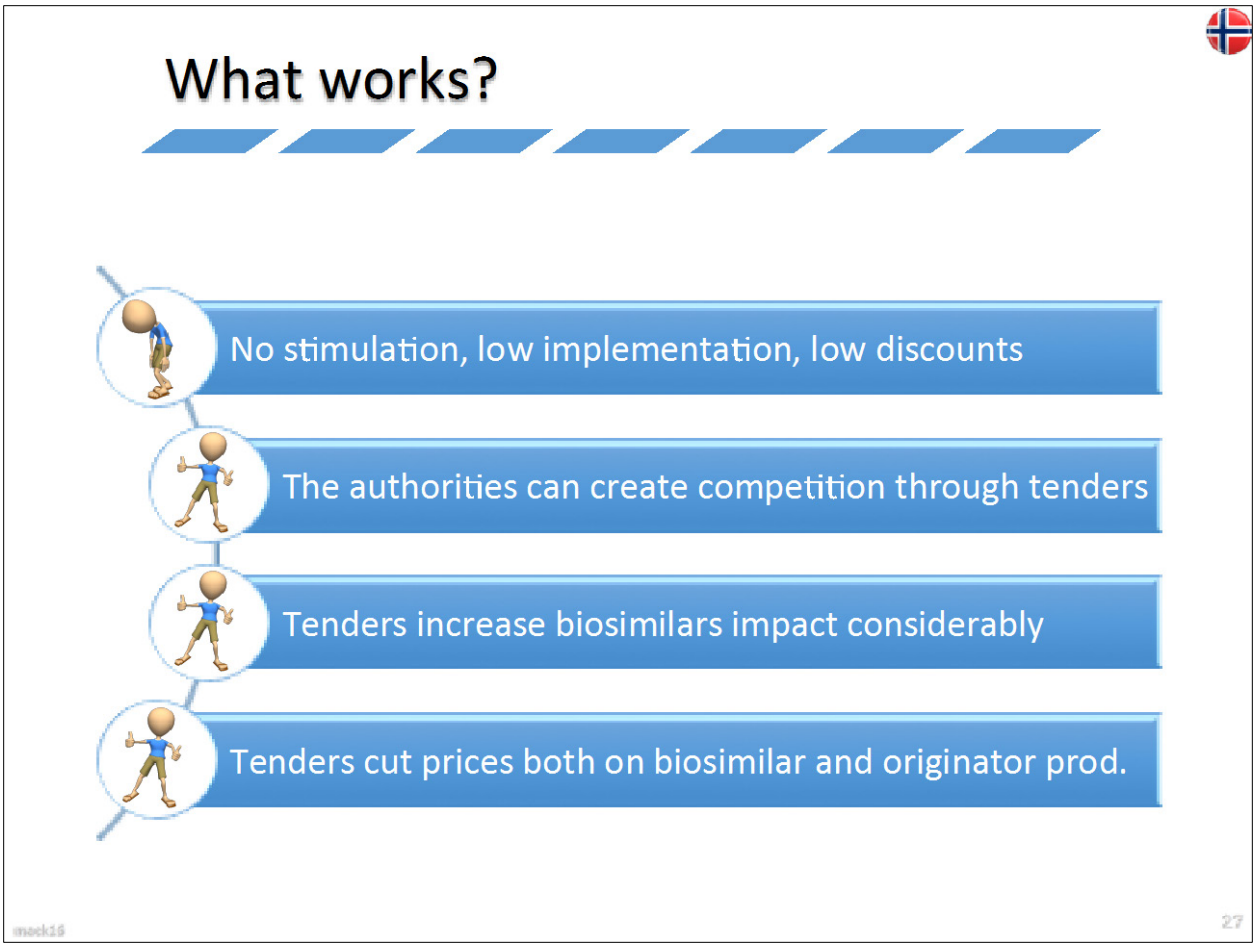
A lesson learned was that, in order to increase biosimilar uptake, patients, health personnel, and payers need to feel that they are safe to use and that there is a requirement to:

- document the effect of biosimilars;
- document the safety of biosimilars (immunogenicity);
- ensure good communication with patients;
- explain why extrapolation is safe;
- ensure support for doctors from their superiors; and,
- provide education for health personnel and patient organizations.

With the introduction of a biosimilar for infliximab, Norway included the biosimilar into an existing national tender for anti-tumor necrosis factor drugs (anti-TNFs), where the class, including biosimilars, compete for both inpatient and outpatient use. The tender is for one year, ranks products per indication based on price, and prohibits parallel export with tender prices. Two years later, a biosimilar for etanercept was included in the same tender.

Uptake has been strong for biosimilars for both infliximab and etanercept, with the latter at a greater rate likely due to experience with the first biosimilar that was launched earlier (and due to enrollment of patients in the NOR-SWITCH study that delayed a non-medical switch to the biosimilar). Biosimilars for infliximab and etanercept currently have a 94% and 60% market share of biologic, with pricing reductions of 69% and 50%, respectively. Six (with more anticipated) additional classes of drugs were recently reorganized to enable a tendering process, and discounts observed have ranged from 50 to 76%. Pricing reductions relative to originator reference price have been observed for biosimilars as well as originators. Similar results have been observed in other Nordic countries, with the exception of Sweden, who signed a deal with the originator manufacturer prior to biosimilar entry that delayed the ability to tender. Savings in Norway are being redirected for use in procuring new innovations, in particular oncology therapies.

In addition to patients being followed in registries, the government of Norway is funding the NOR-SWITCH study, which is a randomized, double-blind, parallel group study to assess the safety and efficacy of switching from originator infliximab to the biosimilar infliximab (Remsima™) in patients with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, and chronic plaque psoriasis. Results are expected in Q4 2016.


What works?
No stimulation, low implementation, low discounts
The authorities can create competition through tenders
Tenders increase biosimilars impact considerably
Tenders cut prices both on biosimilar and originator prod.
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3. Reflection of the Discussion

3.1. Framing the Issues

The introduction of biosimilars in Alberta generates uncertainty that permeates the discussion, creates debate, and provokes a number of tensions within the health system that were the subject of much discussion at the IHE Biosimilars Forum. Biosimilar products are 'similar', and, according to Health Canada and other regulatory agencies, are not identical to originator (reference) biologics. One perspective is that they are similar enough and we likely cannot differentiate between them, so we should encourage competition and utilize biosimilars to reduce healthcare expenditures. Another perspective is that there is uncertainty with biosimilars in the absence of clinical efficacy and safety data like that available for originator biologics, as well as a lack of direct clinical experience by Alberta patients, providers, and payers; we therefore do not know *how* similar they are, and we should differentiate them from reference biologics.

It is not the first time we have faced uncertainty with biologics; when originator biologics were first introduced, we were in a similar position in terms of evidence and experience. The challenge is that, with originator biologics, patients and providers currently have clinical evidence, experience, and, importantly, management control of challenging medical conditions, and there is concern that control might be lost with the introduction of biosimilars, a direction stimulated by an interest in cost savings.

In some respects, we are witnessing a paradigm shift in the biologics space, in that patients and providers initially pulled originator biologics into clinical care to meet unmet medical need, and now payers are interested in pushing biosimilars into care in the interests of improved value for money. Patients and physicians are on the opposite side of the discussion this time. Both are interested in achieving the best health outcomes possible, and both are interested in being good stewards of public health resources. However, there is tension as risks are taken by individuals, with benefits accruing to the community as a whole, and savings are not guaranteed to return to the pharmaceutical or even health budget to fund innovation.

To identify a path forward, we need to understand where best judgement suggests we currently have enough data that biosimilar products are safe and efficacious with no clinically meaningful differences from comparator reference drugs, and where there are gaps. Where there are gaps, we need to understand how we will obtain sufficient data, and how we will recognize when we have achieved this. This begins with an understanding of what questions we need answered, being cognizant of the notion that they may be different questions than previous ones related to biologic therapy. Alberta is not alone in terms of interest in more data to answer questions related to biosimilars, and the decision to make is whether we lead or follow.

Moving forward in pursuing an approach to benefit from new options and opportunities introduced by biosimilars over the long term, an active and sustained competitive market is required in order to increase value for money in a post-patent biologics world. This requirement creates tension related to: how we strike the right balance between rewarding innovation and achieving improved value for public expenditures; how we structure competition to be as fair and inclusive of both originator and biosimilar manufacturers as possible yet support the long-term interest of biosimilar manufacturers to continue to develop new options, given an ability to earn a return on their investment; and how we measure value, factoring in price but also other important value-drivers such as services provided, quality, and reliability.

To get started towards an Alberta approach for biosimilar reimbursement, where we must begin and end is with the patient, both in terms of health outcomes achieved and their experience with the health system in managing the condition to which they have turned to the system for support. The tension between care based upon best evidence and care based upon best value perhaps plays out most impactful for patients, and thoughtful discussion and debate will support good judgement and sound decision-making as policy is developed. This IHE Biosimilars Forum was a good start to begin to inform the approach, and there is much work remaining. The following characterizes key themes that emerged from the discussion and identifies action items for consideration as next steps. Please see Appendix 3 for notes that identify key themes and points from the discussion, as observed during the day by the Chair and Panel and presented to the audience at the wrap-up.

3.2 A Multi-Factorial Approach

Reflecting on the thought-provoking presentations on European approaches and outcomes observed, the discussion identified that the achievement of biosimilar policy objectives in Alberta will likely only occur through a multi-factorial approach that encompasses a number of elements beyond mechanisms to secure the lowest priced biologic. The group identified that we will achieve biosimilar objectives through the combination of:

- effective procurement strategies to capture value;
- clinical efficacy, safety, and economic evidence development and communication;
- education and experience;
- appropriate and enabling incentives to encourage utilization; and,
- active and sustained competition.

All stakeholders were felt to have a role to play, and the group suggested a need to determine a biosimilars "entry package" that captures these elements and articulates stakeholder roles and contributions, including those of biosimilar manufacturers wishing to enter the Alberta market. Going forward, the group expressed strong interest in robust stakeholder engagement to continue the discussion of these elements that will frame and drive the Alberta approach and outcomes achieved with biosimilar introduction. These elements are explored further below.

Procurement strategy to capture value

Much of the discussion of procurement strategy was framed in terms of comments on the Norwegian model (tendering on the basis of best price). Aside from concerns regarding price as the only measure of value, there was discussion of whether we have enough evidence at this time to conclude equivalency of biologic agents and whether it is appropriate to broadly differentiate on price across classes of agents and between originator and biosimilar products for all patient segments and indications. The group highlighted the challenge with monitoring clinical experience and outcomes achieved over time with the potential for patients to switch biologic agent each year or other interval following a tender award. Additionally, there were concerns expressed regarding single sourcing in terms of long-term attractiveness of the market to manufacturers, practical concerns of product supply in the event of supply chain interruption, logistical considerations given substantial private insurance coverage for patients in Alberta that may differ from public insurance, as well as implications regarding sustainability, quality, and consistency of the supporting infrastructure currently available for many biologic treatments (e.g., infusion clinics, patient support programs).

Taking a step back from comments directed at one approach, a number of policy considerations to guide strategy emerged from the discussion. The group highlighted that an Alberta procurement strategy to capture value should:

- differentiate first on the basis of best judgement regarding available clinical evidence, and then on price or other measures of value;
- assess value by more than just price and include other important considerations such as value-added services, quality, and reliability of supply;
- align with interest in prospectively monitoring experience and outcomes, and not create conditions where this is not possible or practical;
- support long-term attractiveness of the market for manufacturers (of originator and biosimilar products) when defining which manufacturers may compete, the number of products that are provided market access for all or some segments of patients or indications, as well as the longevity of reimbursement decisions; and,
- address the sustainability, quality, and consistency of the supporting infrastructure currently available for many biologic treatments (e.g., infusion clinics, patient support programs), as well as practical and logistical considerations related to these elements in the event of public insurance biologic reimbursement differing from that of private insurance.

The group further identified that, as Alberta develops reimbursement policy, there is a need to ensure that it is designed to be sustainable over time, and to anticipate new originator biologics entering the market, the potential for a significant number of biosimilars to enter, as well as a dynamic biologic agent context in terms of indications and place in therapy. The discussion noted that there are meaningful differences between conditions treated/therapeutic areas, classes of biologics, and indications, and it is therefore important to consider the nuances of each when developing reimbursement policy, as opposed to pursuing a blanket biosimilar reimbursement policy that is applied in all situations.

Given a pan-Canadian approach for pharmaceutical economic evaluation and negotiation, the group noted that Alberta will not develop reimbursement policy in isolation from other provinces. The group identified a leadership opportunity for Alberta to work within the pan-Canadian framework to advance biosimilar reimbursement policy at a national level.

Evidence development and performance monitoring

The discussion identified that an important step to get started with biosimilar reimbursement policy in Alberta is to identify where best judgement suggests we currently have enough data that biosimilar products are safe and efficacious with no clinically meaningful differences from comparator reference drugs, and where we do not. From this starting point, for biosimilars to play an increasing and evolving role in the health system, the group discussed a need to continue to build the clinical evidence base for them, including real world evidence development, in order to define what *similarity*, *non-equivalence*, and *non-identical* really mean, and to provide confidence and comfort for patients, providers, payers, and other stakeholders.

The discussion suggested a need for an initial next step to identify the questions we wish to answer over time that will demonstrate where biosimilars can play a useful role, and where they should be avoided. Following this, it was suggested that there is a need to establish a mechanism and leadership/structure to track utilization and outcomes achieved, importantly including those

reported by and valuable to patients, and to regularly report on outcomes relative to policy objectives. It was noted that European and other countries are not as well organized as they could be in terms of gathering this information, and Alberta has a chance to be a leader in this area to help evolve the role of biosimilars, including the potential to require a registry for all new biologic agents. The group noted that Alberta has current registries as well as existing and emerging provincial data assets that can support this effort.

The group observed that this forum was a good start to develop key performance indicators (KPIs) that monitor and report on Alberta's biosimilar experience and outcomes relative to policy objectives, but additional work here is required. Directionally, the group highlighted that safety as well as clinical and economic outcome KPIs are the most important, comparing the performance of biosimilars relative to the performance of originators. Measures of value for public resources were also identified as important KPIs, including measures of pricing (e.g., average price per patient per therapeutic day, segmented into price of originator and biosimilar relative to originator prior to biosimilar introduction, and price evolution over time), as well as originator and biosimilar manufacturer investment and support commitments (e.g., patient support programs, registry support).

Additionally, it was noted that KPIs to demonstrate if utilization of therapies changes as anticipated with the introduction of biosimilars are important, including measures of the appropriateness of any increased utilization of biologics consequent to change in place of therapy given improved value for money. Further, it was noted that there is a need for KPIs to report on utilization of public resources saved by the introduction of biosimilars in terms of increasing access for patients to next generation therapies as they become available.

QuintilesIMS is tracking a number of KPIs in Europe, which may be referenced as a starting point in Alberta. The report can be found at: *http://www.medicinesforeurope.com/docs/IMS-Impact-of-Biosimilar-Competition-2016.pdf*.

Finally, it was reinforced by many participants that it is critical to develop KPIs that broadly track data from the patient perspective, including the patient experience, patient-reported outcomes, quality of life, and economic measures such as productivity and absenteeism.

Education and experience

The group recognized that patients and providers will need to be aligned with biosimilar reimbursement policy in order for Alberta to achieve policy objectives, including utilization of biosimilars as intended. The group highlighted the importance of education appropriate to the Alberta culture and the use of clinical champions to share current evidence and the objectives we are trying to achieve with reimbursement policy, along with the processes and mechanisms established or planned to capture data and answer questions over time to course correct and support future decision-making. Much of the discussion, appropriately, focused on the patient, both in terms of health outcomes achieved and their experience. The group heard anecdotally and through recent survey data that patients have some concerns about physicians and public drug plans making decisions based upon price and not necessarily best available evidence, in particular with the prospect of a change to stable therapy that may have been life altering for them. The group also heard that patients will become more comfortable with biosimilars as their physicians become more experienced and comfortable. Education that encourages direct clinical experience was noted as key, and that it may even eliminate the need for policy tools to shift usual care to better value options.

Value-added enablers

The discussion concluded that many of the incentives utilized in the European context are not applicable to the organization or culture of health care in Alberta. Incentives were reframed for the Alberta context in terms of important value-added infrastructure and investments that are required to enable change in practice. These enablers include both clinic and patient supports, education, experience programs, and infrastructure and investments in product delivery and patient support programs.

It was noted that we might use current infrastructure and investments as a benchmark to articulate expectations for biosimilar product entry. An information gap that was identified is an inventory of current provincial infrastructure and investments. Further, it was noted that there is a need to understand how transitions between value-added enabling elements can be effectively managed following biosimilar introduction, for example patients transitioning between different manufacturer support programs. Finally, the group identified a need to understand practical and logistical considerations related to enabling elements in the event of public insurance biologic reimbursement differing from that of private insurance, and for those that migrate between different public drug plan jurisdictions.

Active and sustained competition

The group recognized that an active and sustained competitive market is required in order for Alberta to benefit from new options and opportunities introduced by biosimilars over the long term. A lesson shared from small molecule generic experience is that there is evidence that driving prices too low leads to disincentives for manufacturers to participate and supply issues, and conversely comparatively high pricing is observed when competition is minimal or absent. The group noted that Alberta will need to consider the:

- inclusiveness of competitive processes with regards to both originator and biosimilars;
- methodology for how value is measured;
- number of products provided market access for all or some segments of patients or indications; and,
- longevity of reimbursement decisions.

The discussion noted that the challenge in order to increase value for money in a post-patent biologics world is to structure competition to be as fair and inclusive of both originator and biosimilar manufacturers as possible yet support long-term interest by biosimilar manufacturers to continue to develop new options given an ability to earn a return on their investment, and to identify how to measure value in a manner that includes price, but also other important value drivers such as services provided, quality, and reliability.

3.3 Summary of Next Steps

The following summarizes a number of next steps that were identified for consideration at this IHE Biosimilars Forum:

1. Identification of a process and leadership for continued stakeholder engagement, including a mechanism to engage patients.

2. Consideration of a leadership role for Alberta to stimulate a pan-Canadian dialogue and identify how the provinces might collaborate for a consistent, responsive, and transparent pan-Canadian approach to biosimilar reimbursement policy.
3. Determination of a biosimilars "entry package" that includes a multi-factorial approach, and articulates stakeholder roles and contributions, including expectations of biosimilar manufacturers wishing to enter the Alberta market.
4. Identification of the clinical efficacy, safety, and economic questions we wish to answer over time that will demonstrate where biosimilars can play a useful role, and where they should be avoided.
5. Establishment of a mechanism (e.g., patient registries) and leadership/structure to prospectively track utilization and outcomes achieved, importantly including those reported by and valuable to patients.
6. Development of key performance indicators and a mechanism to regularly report on them relative to policy objectives.
7. Development of culturally appropriate educational material for patients and providers, as well as clinical champions that share current evidence for biosimilars and the objectives we are trying to achieve with reimbursement policy, along with the processes and mechanisms established or planned to capture data and answer questions over time.
8. Development of an inventory and valuation of current provincial infrastructure and originator manufacturer investments for biologics delivery and patient and other supports, as well as an understanding of how transitions between value-added enabling elements can be effectively managed with biosimilar introduction, including issues related to differences between public and private insurance biologic reimbursement.
9. Identify methodologies to measure and evaluate value, as well as appropriate competition models (including any role for government) that enable an active and sustained competitive market for post-patent biologics.

4. Summary and Concluding Comments

The IHE Biosimilars Forum represented a good start in terms of a broad group of stakeholders coming together to discuss complex and challenging issues related to biosimilar reimbursement. A rich and productive discussion took place, with stakeholders from different perspectives (government, patient and provider associations, clinicians, academics, and originator and biosimilar industry) engaging and sharing experience and considerations to inform an Alberta approach to reimbursement.

Clearly this event was a good start; however, there is much more to do to articulate, implement, and monitor a thoughtful and sustainable Alberta approach. The level of interest and engagement at this event suggests that the stakeholder community is prepared and willing to continuously be engaged to implement some of the next steps emerging from this event, and to participate in similar future forums to evolve the discussion and support Alberta to define and achieve biosimilar reimbursement policy objectives.

Appendix 1: Forum Program

A copy of the IHE Biosimilars Forum program can be found on the following pages.

INSTITUTE OF HEALTH ECONOMICS
ALBERTA CANADA

IHE Biosimilars Forum

THURSDAY, OCTOBER 6, 2016
COAST EDMONTON PLAZA HOTEL
EDMONTON,ALBERTA

9:00 – 9:15 a.m.	Introduction & Welcome • **Dr. Richard Fedorak**
9:15 – 10:15 a.m.	The International Biosimilars Experience: Lessons for Alberta • **Mr. Murray Aitken – Executive Director, QuintilesIMS Institute**
10:15 – 10:45 a.m.	Table Reflection on International Experience
10:45 – 11:00 a.m.	Break
11:00 – 12:00 p.m.	Panel Discussion on International Experience
12:00 – 12:30 p.m.	Lunch
12:30 – 1:30 p.m.	Towards Defining an Alberta Approach: Guiding Principles & Policy Options • **Dr. Asbjørn Mack – Chief Negotiator Pharmaceuticals, LIS, Norway**
1:30 – 2:00 p.m.	Table Reflection on Principles & Policy Options
2:00 – 2:45 p.m.	Panel Discussion on Principles & Policy Options
2:45 – 3:00 p.m.	Break
3:00 – 4:30 p.m.	Panel Discussion: Striking the Right Balance - Key Performance Indicators, Engagement and Targets
4:30 – 5:00 p.m.	Wrap Up Key Themes/Messages • **Dr. Richard Fedorak**
5:00 p.m.	Adjourn

Dr. Richard N Fedorak, MD, FRCPC, FRCP (London), FRSC

Dean of the Faculty of Medicine and Dentistry
Profession of Medicine
Division of Gastroenterology
University of Alberta, Edmonton, Alberta, Canada

Dr. Richard N Fedorak is Dean of the Faculty of Medicine and Dentistry at the University of Alberta, Edmonton, Alberta, Canada. He is also Professor of Medicine in the Division of Gastroenterology at the University of Alberta. Outside of the University Dr. Fedorak is President, Canadian Digestive Health Foundation (CDHF) and Chairman, Research Committee, World Gastroenterology Organization. He is a member of the Medical Staff at both the University of Alberta Hospitals and the Cross Cancer Institute, and is a Consulting Physician at the Stollery Children's Health Centre of Northern Alberta and the Royal Alexandra Hospital. In 1978, Dr. Fedorak received his medical degree with First Class Honours from the University of Alberta, Edmonton, Alberta, Canada. His postdoctoral training included an internship at the University of Western Ontario, in London, Ontario, and residency training in General Internal Medicine at the University of Toronto. His Gastroenterology Clinical and Research Fellowship training was carried out at the University of Chicago and Columbia University, New York. In 1987, Dr. Fedorak returned to the University of Alberta as an Alberta Heritage Foundation for Medical Research Clinical Investigator. A recipient of numerous awards, research fellowships and grants, Dr. Fedorak is a recognized expert in inflammatory bowel disease. He has an active basic gastrointestinal research laboratory in the area of mucosal immunology, inflammation, and membrane function and structure. In addition, he leads a large gastrointestinal disease clinical research group. Dr. Fedorak serves on multiple national and international scientific advisory boards. He has published over 500 peer-reviewed manuscripts and book chapters, produced two patents on colonic-specific drug delivery, and has lectured around the world. He has multiple grant review committee memberships and editorial positions with front ranked gastrointestinal journals. In 2011 Dr. Fedorak founded a University spin-out company, Metabolomic Technologies Inc. (www.metabolomicttechnologies.ca), which is developing a patented urine-based screening test for detection of colonic adenomatous polyps as its flagship diagnostic test for clinical practice. Dr. Fedorak has served as President of the Canadian Association of Gastroenterology, President of the University of Alberta Hospital Medical Staff, President of the Alberta Society of Gastroenterology, President of the World Congress of Gastroenterology Bid Federation, General Secretary of the Pan American Congress of Gastroenterology and President of the World Congress of Gastroenterology. Dr. Fedorak has been appointed as a Fellow, Royal College of Physicians, London, Fellow, Canadian Academy of Health Sciences and Fellow of the Royal Society of Canada.

Murray Aitken

Senior Vice President, IMS Health
Executive Director, QuintilesIMS Institute
New York, USA

Murray Aitken is a senior vice president at QuintilesIMS (formerly known as IMS Health) and the executive director of The QuintilesIMS Institute. Mr. Aitken is a renowned healthcare expert on addressing the challenges facing the global healthcare industry and prospects for improving patient outcomes, managing costs and maximizing access through better use of healthcare data and information. Established in 2011, The Institute provides global policy setters and decision makers with objective, transformational insights into healthcare dynamics derived from granular analysis of information. Throughout his 15-year tenure at QuintilesIMS, Mr. Aitken served in various roles responsible for healthcare insights, corporate strategy, and consulting and services. Prior, Mr. Aitken was a partner at McKinsey &

Company in New Jersey and Los Angeles in the U.S. and in Seoul, Korea, covering a broad range of industries, including life sciences and consumer goods. He holds an MBA, with distinction from Harvard University and Masters of Commerce from the University of Auckland in New Zealand. A frequent speaker on the international healthcare industry circuit, Mr. Aitken's perspectives are widely covered in the business/financial press, including The Wall Street Journal, The Financial Times, Fortune, Time, The Associated Press, Bloomberg Business, Reuters, CNBC as well as in local market publications across Europe, Asia and Latin America.

Dr. Asbjørn Mack

Chief Negotiator Pharmaceuticals
LIS (Drug Procurement Cooperation)
Department in HINAS (Norwegian Health Procurement)
Oslo, Norway

Dr. Asbjørn Mack was educated as a Doctor of Medicine at the University of Oslo and a Business Economist at the Norwegian Business School. His current position is Chief Negotiator Pharmaceuticals in Oslo, Norway with LIS (Drug Procurement Cooperation). LIS manages all tenders for pharmaceuticals paid for by the hospitals and is owned by the Regional Health Authorities. He is responsible for analyzing hospital use of drugs and providing advice on how to use the LIS tenders to gain more health resources from a fixed budget. He has a special focus on the use of biosimilars. He is also responsible for negotiating prices on new expensive drugs paid for by the hospitals to secure cost-effective use. He is a member of all specialist committees in LIS. Previously he set up Drammen Occupational Medical Service in 1983 and worked as General Manager/Industrial Medical Officer until a move to the pharmaceutical industry in 1990. He started with Novo Nordisk Pharma followed by Aventis Pharma, Fujisawa Scandinavia, Sanofi-Aventis, Wyeth and Pfizer. His main focus during 25 years in the pharmaceutical industry has been market access oriented; pricing, reimbursement, economic analyses and contact with health authorities. His last position as Health & Value Lead in Pfizer included a focus on biosimilars. He was a member of the Health Economics Committee in the Association of the Pharmaceutical Industry in Norway from 2005 to end 2014, and a member of the Biosimilar Ad hoc Committee from the start in 2010 to end 2014.

Gail Attara

President & CEO GI (Gastrointestinal) Society
Vancouver, British Columbia, Canada

Gail Attara began with the GI Society (www.badgut.org) in 1996 as Executive Director of the organization's sister charity, The Canadian Society of Intestinal Research, and led that organization from a small BC charity into a national presence before co-founding the GI Society in 2008. The two organizations collaborate to provide useable evidence-based information to gastrointestinal and liver patients in Canada. Gail's motto, 'the patient comes first', directs her resolve for patient-focused health care and commitment to increasing awareness about the seriousness of digestive illnesses. Gail has a solid background in public relations and fundraising and is an active community volunteer in Canada serving on numerous Boards, and overseas, where she has worked with orphans. She is also a published freelance author. Gail has been an invited speaker coast-to-coast on numerous occasions, to wide-ranging audiences, including physicians, patients, pharmacists, and health care decision-makers. Participating as a member of the Best Medicines Coalition since 2005, Gail is now serving her seventh year as Chair. Gail is a member of the Consensus Framework for Ethical Collaboration among health care stakeholders, the Innovative Medicines Canada Stakeholder and Partnerships Advisory Group, and is on the CADTH Patient Community

Liaison Forum, to name a few initiatives. Gail is also co-founder of Advocacy Boot Camp Inc., where she fulfills her goal of expanding the network of knowledgeable patient advocates working in health.

Dr. Stephanie Keeling

Associate Professor of Medicine
Division of Rheumatology
University of Alberta, Edmonton, Alberta, Canada

Dr. Stephanie Keeling is an Associate Professor of Medicine at the University of Alberta Division of Rheumatology. She completed her Master's in Experimental Medicine with Walter Maksymowych studying inflammatory back pain in spondyloarthritis. Since that time, she has established the University of Alberta Lupus Program with conjoint clinics in Dermatology. She has also collaborated with Cardiology at the Mazankowski Heart Institute and conducted a Cardiovascular Risk Reduction Clinic for Inflammatory Rheumatic Diseases which has now evolved into the new ON-Traac (On Treating Rheumatoid Arthritis, Access to Care) program with co-director Steven Katz. This treat-to-target clinic for inflammatory arthritis includes co-morbidity management for osteoporosis and cardiovascular risk utilizing a shared care model with allied health professionals. She is currently the principal investigator of GRADE-based recommendations for the diagnosis and management of lupus in Canada. She also participates in the teaching of medical students, residents and fellows.

Steve Long

S. C. Long Consulting Ltd.
Calgary, Alberta, Canada

Steve has held progressively senior pharmacy leadership positions in hospital, government and community pharmacy practice environments. He has held operational responsibility for pharmacy systems within the hospitals of the Calgary Health Region, pharmaceutical policy creation and strategy execution roles for the Alberta Government and provided insight into national public policy and thought leadership within Shoppers Drug Mart. Through these opportunities Steve has gained insight into formulary and drug listing decisions for hospitals, public and private payers, conceived and implemented pharmacy practice change and designed drug benefit plans. Steve supports clients in addressing challenges by applying his varied and broad insights and experience, by listening and communicating in an open and transparent manner and by offering creative solutions which meet the needs of patients and other health system stakeholders. Steve attained a Bachelor of Science and Bachelor of Science in Pharmacy from the University of Alberta, a Residency in Hospital Pharmacy from the Ottawa General Hospital and his Master of Business Administration from the University of Calgary. Steve currently works as a pharmacy and health system consultant based in Calgary, Alberta, Canada.

Appendix 2: Forum Participants

First Name	Last Name	Organization
Michele	Evans	Alberta Health
Chad	Mitchell	Alberta Health
Andrea	Nagle	Alberta Health
Janice	Leung	Alberta Health
John	Sproule	Alberta Health
Justin	Reimer	Alberta Health
Michael	Guirguis	Alberta Health Services
Jeremy	Slobodan	Alberta Health Services
Carole	Chambers	Alberta Health Services
Erwin	Friessen	Alberta Health Services
Anil	Joy	Alberta Health Services
Doug	Stewart	Alberta Health Services
Alex	Charlton	Alberta Health Services
Hubert	Eng	Economic Development & Trade
Farid	Foroud	Economic Development & Trade
Lori	Querengesser	Economic Development & Trade
Hameed	Khan	Alberta Innovates - Health Solutions
Jeff	Whissell	Alberta Pharmacists Association
Greg	Eberhart	College of Pharmacists
Janet	Gunderson	Canadian Arthritis Patient Alliance
Gail	Attara	Gastrointestinal Society
Andrew	Spiegel	Global Colon Cancer
Bill	Gaudette	Health Coalition of Alberta
Mina	Mawani	Crohn's & Colitis Canada
Catherine	Mulvale	Canadian Digestive Health Foundation
Michael	Riley	Alliance for Safe Biologics
Wendy	Sauve	Canadian Association for Porphyria
Aida	Fernandes	Crohn's and Colitis Canada
Keith	Gilchrist	Janssen
David	Zante	Janssen
Heather	Francis	Roche Canada
Ilona	Torontali	Roche Canada
Cindy	Schurman	Abbvie
David	Link	Abbvie

First Name	Last Name	Organization
Michael	Gingras	Amgen
Dwayne	Stewart	Amgen
Patrick	Manfred	Takeda
Dan	Ekstrand	GlaxoSmithKline
Jennifer	Chan	Merck Canada
Kar	Leung	Merck Canada
Daria	Horbay	Pfizer Canada
Kimberly	Shulha	Novartis Canada
Bill	Gowen	Sanofi
Lydia	Lanman	Eli Lilly
Michael	Flood	BioAlberta
Norine	Primeau-Menzies	McKesson
Brent	Korte	Impact Consulting
Anne	Babineau	Innovative Medicines Canada
Heather	West	ApoBiologix
Ross	Wallace	Santis Health
Phil	Jacobs	Institute of Health Economics
Steve	Long	S. C. Long Consulting Ltd.
Richard	Fedorak	University of Alberta
Stephanie	Keeling	University of Alberta
John	Bachynsky	University of Alberta
Neil	Davies	University of Alberta
Joanne	Homik	University of Alberta
Jill	Hall	University of Alberta
Robert	Gniadecki	University of Alberta
Raimar	Loebenberg	University of Alberta
Vivian	Huang	University of Alberta
Dianne	Mosher	University of Calgary
Cynthia	Seow	University of Calgary
Murray	Aitken	QuintilesIMS Institute
Asbjørn	Mack	LIS (Drug Procurement Cooperation) Norway

Appendix 3: Summary of Themes Identified During the Forum

Session 1: The International Biosimilars Experience – Lessons for Alberta

Key takeaways:

1. Education – both patients and healthcare providers
2. Real world evidence needed – outcomes, safety data, adherence to support #1
3. Expand experience – to support #1
4. Maintain competition → sustainability
5. Ensure biosimilar outpatient programs are "patient" similar

Session 2: Towards Defining an Alberta Approach – Guiding Principles & Policy Options

Key takeaways:

1. Switching is not approved in Canada
2. Treatment based on price is okay if knowledge exists about the product
3. Policy today needs to be sustainable into the future
4. Physician/healthcare worker leadership is needed
5. Consultation with all stakeholders is required
6. Registries should be mandatory with good patient-reported outcomes and costing data
7. Know about patient anxieties relative to switching patient programs
8. Guidance for physicians and patients needs to be explicit and appropriate to culture
9. Competition of all players – biosimilars and originators
10. Multi-factorial approach where price/volume is only one aspect

More Key Points

- Performance indicators
    - Outcomes, safety, price, volume, unmet needs
    - Freeing up resources for next generation treatments → promote innovation
    - Tracking of biosimilar use
- Tension in the entire system
    - Patient ⇔ Provider ⇔ Industry ⇔ Government (Ministry of Health, Cabinet)
- Develop a policy at the core that makes sense and stand behind it
- Listen to the patients, and engage at different steps
- Teach patients to be good advocates by educating them

This report provides a summary of the IHE Biosimilars Forum engagement exercise that took place on October 6, 2016 in Edmonton. The intent of the forum was to inform Alberta biosimilar reimbursement policy by sharing international experiences in this area, and the perspectives of key stakeholders.

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