International Federation on Ageing

Emerging Trends in Ophthalmic Biosimilars Policy in Canada

Roundtable Summary Report

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Introduction

Over 2 million Canadians are currently living with vision loss as a result of retinal diseases. The current most advanced treatments available for eye conditions include biologic anti-VEGF treatment as a way to slow vision loss in people with wet age-related macular degeneration (wAMD) or diabetic retinopathy (DR). However, with patents on the anti-VEGF biologics soon to expire, there is an emerging trend toward the use of biosimilars in ophthalmic practice. Government policies in India, Europe, and the United States of America (USA) to procure and implement biosimilars are not only about the safety and efficacy of the regimen, but also the potential cost-savings.

In Canada, various federal and provincial consultations have informed the broad landscape of biosimilars policies, yet sparse attention has been given to specific fields such as ophthalmology. Awareness and education of biosimilars (rather than the originator) as a treatment option is an important step towards the development of policies that support safe and effective management and treatment, specific to the needs of patients and their medical conditions.

To position this emerging field in a Canadian context with a focus on awareness and education of physician and patients, and the barriers of implementing biosimilar policies globally, the International Federation on Ageing (IFA) convened a virtual roundtable discussion on 'Emerging Trends in Ophthalmic Biosimilars Policy in Canada'. Leaders of civil society and patient advocacy groups, alongside retinal specialists and public policy experts shared perspectives in this forum on biosimilar policies and practice with respect to the changing vision health landscape in Canada. The meeting unpacked details related to physician and patient experiences and the level of awareness of biosimilars, along with the challenges and successes of implementing biosimilars policies globally, and the potential impact of mandatory non-medical switching to biosimilars policies on patients in Canada.

Synthesis of the Roundtable

Comparison of Global Biosimilar Policies: A closer look at safety, efficacy, and education

Biosimilars are not new, and it is important to note they are highly regulated medicines available at a lower cost with no difference in safety and efficacy with their counterpart biologics. There is a lot of misinformation about biosimilars perceived to be of lower quality or less efficacious due to their lower price.

Expert speaker Ms. Julianna Reed (Executive Director, The Biosimilars Forum) explained that biosimilars undergo significant analytical, clinical, and non-clinical studies to demonstrate biosimilarity with their reference product. Since there is dependency on previous findings regarding the originator biologic to support approval of biosimilars, it allows for a shorter and less costly biosimilar drug development process which is on average 6-8 years.

Safety and efficacy are crucial to build provider and patient confidence in biosimilars, but just as important is accurate timely information. Stakeholder education and engagement are key pillars for successful uptake of biosimilars.

Global Perspective on Biosimilar Markets and Sustainability

Data from the IQVIA Institute for Human Data Science presented by Mr. Murray Aitken (Executive Director, IQVIA) suggested that the introduction of biosimilars in most European markets increased competition, resulting in lower costs and increased access. In Europe and the USA, biosimilars assume up to 60% of the total market of biologics merely after two years of launch, highlighting the success of biosimilars uptake. Concurrently there has also been a decline in unit prices of biologics to compete with biosimilars, which has generated significant savings and improved access due to affordability. Although there has been a rise in patient access since the introduction of biosimilars, this trend is not true for all biologics due to the complexity of individual markets.

Anecdotal evidence suggests that biosimilars appear to help improving access due to reduced costs, however the long-term impact on the patient and the health care system is somewhat less clear at this stage of implementation. The criteria for a sustainable biosimilars market outlined by Mr. Aitken is dependent upon access to biologics upon biosimilar entry; clearly defined regulatory process, such as treatment guidelines for physicians along with switching and substitution policies; competitive pressure to drive uptake of biologics and biosimilars; incentives for patients and prescribers; and awareness and education of the benefits of biosimilars.

Patient and Physician Experience with Ophthalmic Biosimilars from India

Biosimilars in India is a relatively mature field in comparison to other countries. The first biosimilar was approved in 2000 and the first ophthalmic biosimilar for ranibizumab in 2015. In Europe biosimilars were on the market in 2006, for Canada it was 2009, and the USA 2015. Dr. Ashish Sharma (Consultant Retina and Head Research, Lotus Eye Hospital and Institute) emphasized the robust biosimilar approval process by the regulatory authorities in India. As a retinal specialist Dr Sharma noted, two years since its launch in 2018, the biosimilar ranibizumab had a larger market share that the reference biologic.

Initially there was slow uptake of biosimilars in India. Through education to combat the nocebo effect amongst clinicians coupled with real-world data demonstrating high safety and efficacy after switching, usage of biosimilars increased. Interesting to mention is that since majority of the patients in India do not research about the new medicines, it is crucial for physicians to be educated on biosimilars to provide confidence to their patients.

Biosimilars Policies: The European and North American Landscape

Europe is recognized as a mature biosimilars market underpinned with gold standard policies using a collaborative, patient-centred approach. Mr. Michael Reilly (Executive Director, Alliance for Safe Biologic Medicines) described in an expert presentation, key elements to the development of effective policy. This includes regular multi-stakeholder consultations held by the European Commission; discussions about switching among providers and patients toward a common understanding; prioritizing patient education about biosimilars; and reinvesting savings from the use of biosimilar into the healthcare system.

Studies have revealed that physicians have a degree of confidence and comfort with the use of biosimilars with naïve patients based on rigorous scientific evidence. The patient physician relationship however remains is central to disease management and treatment decisions. There is a clear opposition to non-medical switching from the originator (biologic) and the biosimilar. The mere absence of negative data is not sufficient to build confidence with physicians, instead there is a need for switching studies that show positive patient outcomes.

Two fundamental principles underpin the process to achieve good patient-focussed outcomes. Physicians should have the freedom to determine the most effective and safe treatment, based on scientific evidence and clinical experience, for the patient taking into consideration duration of the disease and current treatment regime. Second is that multi-winner, instead of single-winner tender system should be used to ensure continuity of biosimilars supply and healthy competition.

Key Messages

Safety, efficacy, regulation, uptake, competition, reimbursement, switching, access, and sustainability were key topics explored this interactive dialogue.

Biosimilars are a group of highly regulated safe and effective medicines available at a lower cost than the originator. However, lower cost does not reflect lower quality. Rather, the less expensive biosimilars, in comparison to biologics, may support greater competition and lead to improved access to medicines. The regulatory process is robust with significant experiments to demonstrate biosimilarity with the reference product, taking several years to develop and approve a biosimilar, underscoring that the safety and efficacy of biosimilars is not compromised.

India, Europe, and the USA have witnessed higher use of biosimilars compared with the reference biologic within 2 years of launch. The successful uptake of biosimilars in Europe specifically is attributed to policies created by a collaborative, patient-focused approach and reimbursement of multiple products competing on level playing field, expanding patient/physician choice of treatment.

There is not one European country that has ceased the reimbursement of the originator biologic product through an arbitrary government fiat as seen in the Canadian provinces of Alberta and British Columbia through a non-medical forced switching policies. Therefore, the European experience has demonstrated that forced substitution is not necessary to achieve high biosimilars uptake as well as generate savings.

Globally, there has been an increase in patient access since the introduction of biosimilars across the therapeutic areas of rheumatology, oncology, gastroenterology, and ophthalmology. Nevertheless, sustainability of the biosimilars market is not only dependent on access, but other elements including regulation, competitive pressure, incentives, and awareness. It is important to continue monitoring and evaluating to measure the success of biosimilars policies, for instance European and American surveys have demonstrated physicians and patients are confident and comfortable with biosimilars.

The common themes that emerged from the roundtable discussion include the need for evidence, engagement, education, and advocacy to shape and influence biosimilars policy. Worldwide there is growing policy advancement towards the use of biosimilars driven largely by the potential cost-savings. Yet there is an increasing concern from patient and advocacy organizations about the basis for policies and the impact on current and future patients. While the cost-savings proposition is most certainly a driving force for the policies, this must be balanced with the needs and values of patients and clinicians, while also protecting vision outcomes. Hence, there is a need for data/evidence to demonstrate the influence of the current biosimilars policies on patients and providers. The evidence gathered can also be used to engage multi-stakeholders (patients, providers, manufacturers, policymakers) in the development of future biosimilars policies.

Comprehensive patient and physician education based on trustworthy and updated sources of health information is another integral element of a sustainable vision health plan and policy framework for the appropriate use of biosimilars in ophthalmology. Not only is it an effective strategy to improve confidence in biosimilars, but to also bring patient and provider voices in policy development through advocacy efforts to ensure they maintain control over their conditions by freedom of choice to make decisions, as treatment plans are not one size fits all. Involving all relevant stakeholders when trying to influence and shape biosimilars policies is crucial as they are most familiar with biosimilars and most impacted.

Recommendations

There is a need for a defined set of actions to ensure the safe, effective, and appropriate management and treatment for patients with retinal diseases in the context of emerging biosimilar policies:

1. **Targeted education campaigns for both patients and providers**
   Patient and professional education is a cornerstone for the successful uptake of new medicines, including biosimilars. Tailored and updated evidence-based resources must be accessible to health care professionals, patients, and their families.

2. **Ensuring policies are evidence-based, patient-centred, and improve access to treatments**
   A universal, one-size fits all biosimilar policy approach is not effective nor appropriate. Ophthalmic biosimilars policies must be informed by clinical evidence, rather than driven largely by cost. Appropriate exemptions that respect the efficacy and outcomes of current patient treatment is a key element of good policy, while ensuring continuity of care, access to medications, and low cost.

3. **Inclusion of end-users in policy discussions**
   Biosimilar policies in British Columbia, Alberta, Manitoba, Quebec, New Brunswick, and Nova Scotia do not allow for physician and patient choice. Patients, in consultation with the treating physician, should be able to decide on a treat ment plan that is clinically informed, rather than risk changes in vision due to forced switching. Ophthalmic biosimilar policies should be developed in discussion with stakeholders, involving providers and patients, and considering their impact on the end-users including the caregivers.

Conclusion

To adequately address the multi-layered barriers in access to treatments for retinal diseases, biosimilars in ophthalmology creates an opportunity to expand vision health options for millions worldwide. However, biosimilars in ophthalmology, especially in Canada, is a new and emerging field in the treatment of eye conditions. Therefore, it is critical to build capacity to give voices to global experts, namely clinicians, patients, caregivers, and advocates to help inform the development of ophthalmic biosimilar policies, alongside the urgent creation of evidence-based educational materials, guidelines, and protocols.

Building upon the experiences across jurisdictions and specialties on biosimilar policies, special attention must be applied in the ophthalmology context given the nature, duration, and impact of the treatment intervention. To benefit the health of their populations, governments must develop policies that move the biosimilar discussion beyond an economic savings model toward the health and well being of patients. This begins with interdisciplinary and multi-sectoral collaboration and targeted advocacy efforts. All stakeholders must commit to advocating to shape and influence ophthalmic biosimilars policies which translate into physician and patient choice in selecting the safe, appropriate, and effective treatment. Commitment to consultations between patients and clinicians in determining the most appropriate treatment option for retinal diseases must underpin ophthalmic biosimilar policies to achieve the goal of sustainable access.

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