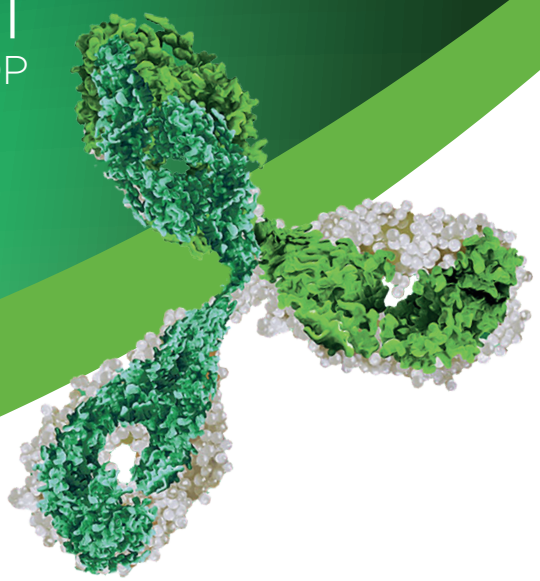
YOUR PATIENTS, YOUR GOVERNMENT

MULTIDISCIPLINARY FORUM & WORKSHOP
FOR BIOSIMILAR MEDICINES



EVENT REPORT

2 OCTOBER, SYDNEY
NSW PARLIAMENT HOUSE

GBMA Education acknowledges the provision of funding by the Australian Government to present this event.

GBMA EDUCATION

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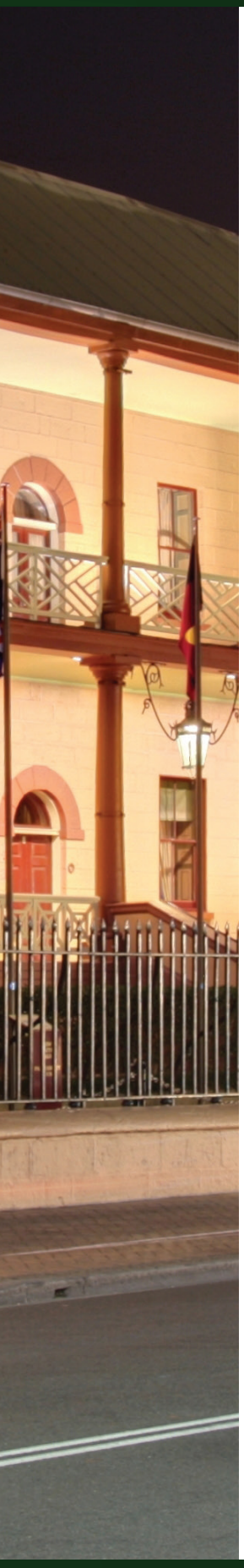


Event Report

GBMA EDUCATION

Introduction

Overview

The Biosimilar Education Grant was awarded to GBMA Education in April 2018 with the objective of increasing confidence in the use of biosimilar brands of biological medicines. To help support the objectives of the grant, GBMA Education hosted the *Your Patients, Your Government* Multidisciplinary Forum and Workshop for biosimilar medicines. This event was designed to facilitate an open and solution-driven discussion between the healthcare sector and government on the key recurring topics surrounding biosimilar medicines in Australia.

Rationale

GBMA Education recognised that, in order to effectively support confidence in biosimilar medicines in Australia, it is imperative that all relevant parties first understand the concerns that exist across the Australian healthcare system. It was observed that while many conversations have been held in the past about biosimilar medicines, these were predominantly conducted with specific groups individually (i.e. specialist, GP or hospital and community pharmacist groups) and that there was an opportunity to further the biosimilar medicine discussion by bringing together all stakeholders to collaboratively discuss biosimilar medicines – to learn from peers and share different perspectives and concerns.

To support such a multidisciplinary approach, GBMA Education designed a unique workshop format dedicated to the discussion of biosimilar medicines and designed to facilitate peer-to-peer learning and constructive debate on this very important topic.

By bringing together the various stakeholders and representatives, the aim was to reduce the barriers that prevent collaborative resolutions that can occur when people only share their views with others of the same perspective.

Three workshops were defined based on the recurring objections that have arisen to date:

- Health Economics and Sustainability of the PBS
- Tracking and Traceability, and Pharmacovigilance
- Patient-Centric Care and the 'Human Factor'

Findings from the workshop discussions will be used to help inform future activities under the Biosimilar Education Grant.

Format

Following a keynote address by the Hon Greg Hunt, Minister for Health and an opening panel, attendees moved to one of three allocated rooms where they participated in the three 30-minute workshops, which were conducted in parallel creating a total of nine workshop discussions across the evening.

Recruitment of an expert panel to lead each workshop was critical to drive attendance and ensure valuable discussions were held. Each panel consisted of a Chair and 2-3 panellists with panellists rotating between rooms. The keynote address and opening panel for the forum were livestreamed nationally to the broader healthcare sector.

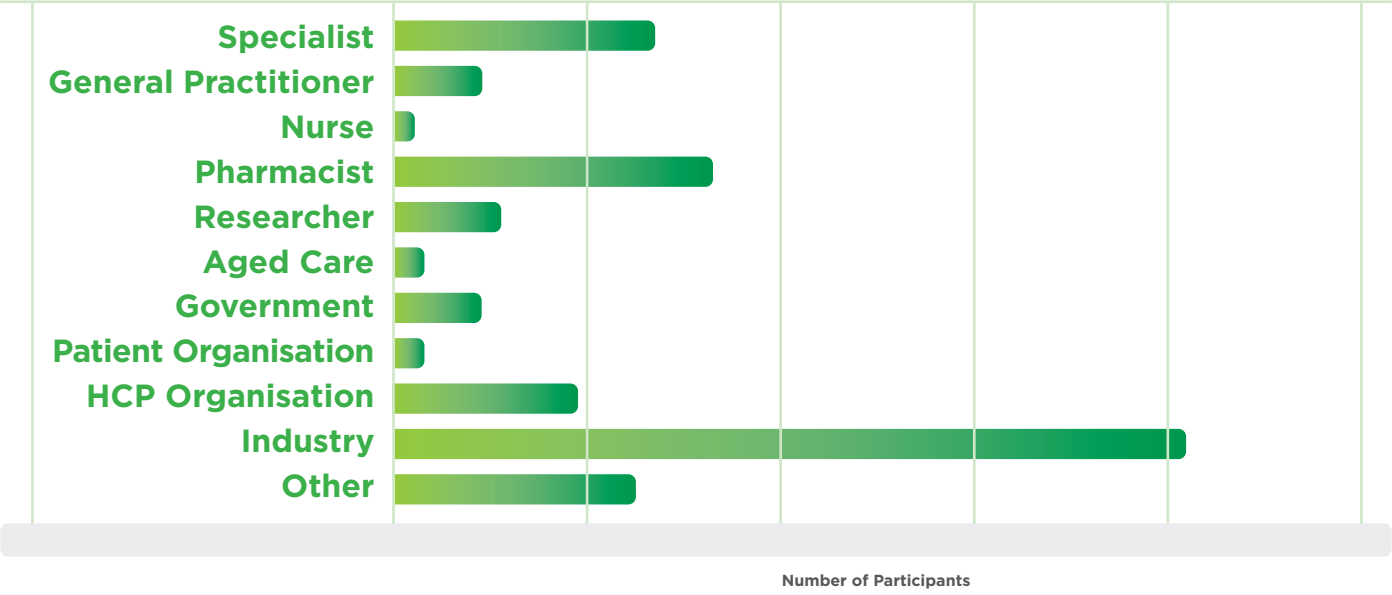
Live polling was conducted throughout the workshops to gather insights and facilitate audience participation. Comprehensive handouts were distributed in advance to accompany each workshop, providing attendees with the required background information to support informed discussions.

Audience

Representatives from across the Australian healthcare sector were invited to attend, with a broad cross section in attendance:

Audience size varied across the three rooms with a cross section of different healthcare professionals as well as industry and Government officials. Each room also had a slightly different setup and size in order to facilitate varying discussions across the same topics

- Auditorium - 60 participants, theatre setup with panel presentation format
- Members Dining Room - 38 participants, cabaret setup with panel presentation format
- Preston Stanley Room - 29 participants, intimate cabaret setup



Executive Summary

Overall sentiment from attending healthcare professionals shows there is confidence in the use of biosimilar medicines for treatment-naive patients or with a single switch, however, concerns remain around a perceived lack of evidence to support multiple switches between brands of the same biological medicine:

"The concerns about multiple switching, one way to fix that is to say I want this patient to be on that brand, and then tick the [brand substitution not allowed] box." [Hospital pharmacist]

There appears to be misconceptions between healthcare professionals about what each party can deliver:

"Most [pharmacists] don't see a lot of biologics in an average week or month. It's not really something you can do over a counter in one go. And the majority of pharmacies have neither the capacity nor the private space to be able to do that." [Specialist]

"Sixty-six percent of community pharmacies have a private consulting room. In my pharmacy I have two rooms - so we do have the infrastructure." [Community pharmacist]

Understanding of the complexities of the PBS system was low overall, with many attendees seeking to understand the pricing policies that will help support the sustainability of the PBS, as well as the concept of 'a-flagging'.

Audience polling demonstrated that many attendees admitted to a low understanding of the TGA's pharmacovigilance program, with many highlighting their concern about underreported adverse events due to the voluntary reporting requirements for healthcare professionals.

Discussions on patient-centric care highlighted that the level of detail provided to patients about biosimilar medicines varies between healthcare professionals:

"Do we need to make a big fuss about it being different? Is that going to be more unsettling than helpful?" [Community pharmacist]

"From the patient perspective, we just need to understand what it's about and why we're doing it and whether it's safe for us to be on that medicine." [Patient representative]

Overall, the evening was a great success and achieved its objective of facilitating robust discussions with a multidisciplinary audience of the healthcare sector, highlighting key areas of concern and opportunities for biosimilar medicines. Furthermore, considerable positive feedback was received from participants following the event.

Issues raised

- Pharmacists, GPs and specialists in attendance had differing views on biosimilar medicines, and what each profession's role is in the management of patients who are treated with biosimilar medicines i.e. patient counselling, device training etc.
    - For example, specialists present at the workshop were not aware that many pharmacies have a private consulting room
- Attendees suggested that there is a need for closer alignment between healthcare professionals to support better patient care, specifically regarding consistency in communication and alignment of expectations.
- In order to understand how biosimilar medicines contribute to the sustainability of the healthcare system, attendees suggested there was a need for a greater understanding of how the PBS system works.
    - There were multiple queries brought to the forefront throughout the evening about how price disclosure works
- To support the understanding of biological and biosimilar medicines, attendees noted that consistent educational materials could be developed to help facilitate discussions between patients and healthcare professionals.

Next Steps

Findings from the workshop discussions will be utilised to help inform and guide the focus of future activities under the Biosimilar Education Grant. GBMA Education notes that some of the issues raised may sit outside the scope of the Biosimilar Education Grant.
Please note, as each workshop topic was run three times over the evening with each of the three separate audience groups, this report collates the discussions across the nine workshops into the three topics. Please refer to the workshop summary reports for summaries of the individual discussion that took place for reach topic.

Disclaimer:

Issues derived from the workshops are based on discussions that took place and do not reflect Government policy.

World-class Healthcare for Australians and Our

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MULTIDISCIPLINARY FORUM & WORKSHOP FOR BIOSIMILAR MEDICINES

Keynote address – Hon Greg Hunt MP, Minister for Health.

Summary

Minister Hunt opened the evening with Piniella's story, a woman with stage 4 lung cancer who received life-saving treatment with a new biological therapy this year. He noted that, on the same day that this medicine became PBS-listed, two new biosimilar medicines also became available:

"To have those two listings of new biosimilars on the same day as a breakthrough biologic [originator], is to see the entire train in process."

"This is about the science of a whole new wave of medicines... [monoclonal antibodies] can offer immense breakthroughs in treatments that were never possible previously."

Ten years ago, biological medicines represented 4% of the PBS, now they represent 25% of the PBS. Minister Hunt stressed that this is why biosimilar medicines are so important to support the sustainability of the healthcare system by bringing down the cost of these medicines.

Minister Hunt went on to explain how the listing of a biosimilar medicine leads to a 25% price reduction of comparator brands, enabling the Government to invest these cost savings across the healthcare system. He referenced the billion-dollar investment in primary care under the new long-term National Health Plan as an example of such investments, made possible in part by the availability of biosimilar medicines.

Minister Hunt concluded by acknowledging the Biosimilar Education Grant awarded to GBMA Education, stating that this commitment:

"makes it clear that we support, believe in and agree with the safety and effectiveness of biosimilar medicines and that we are going to facilitate their uptake."

Health Economics & Sustainability of the PBS

Penny Shakespeare
Deputy Secretary
for Health Financing,
Department of Health
CHAIR

Dr Mona Marabani
Past President of the
Australian Rheumatology
Association and Co-Chair
of the Biosimilars
Working Group

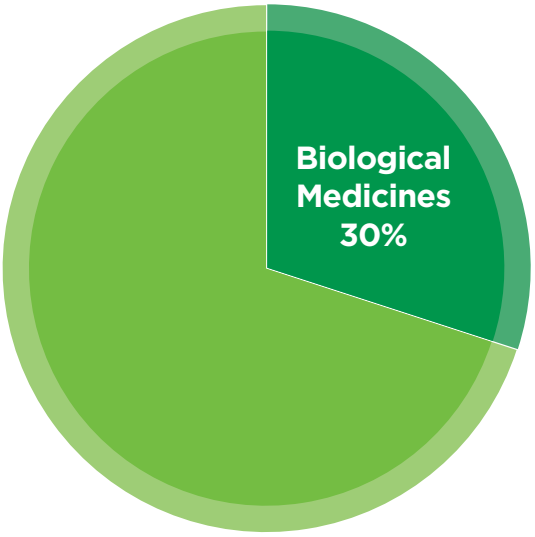
David Ford
Executive Director Pharmacy
and Redevelopment,
North East Health

The Health Economics and Sustainability of the PBS workshop was opened by Ms Shakespeare with a 10-minute overview of the Pharmaceutical Benefits Scheme (PBS), including PBS data on biological medicines:

Top 10 PBS Drugs by Highest Government Cost, 2017-18

Rank	Drug name	PBS-subsidised Prescriptions	Government Cost
1	SOFOSBUVIR + VELPATASVIR	31,047	$695,021,028
2	**ADALIMUMAB**	228,048	**$320,374,082**
3	**AFLIBERCEPT**	239,284	**$304,212,258**
4	LEDIPASVIR + SOFOSBUVIR	10,976	$244,606,914
5	**NIVOLUMAB**	41,839	**$208,068,092**
6	SOFOSBUVIR	10,439	$204,285,271
7	**RANIBIZUMAB**	160,133	**$200,472,514**
8	**DENOSUMAB**	648,197	**$182,104,888**
9	**TRASTUZUMAB**	55,782	**$169,401,131**
10	**INSULIN GLARGINE**	389,177	**$145,203,345**

Total PBS Expenditure 2017-18 was $11.7 billion



Ms Shakespeare noted that from the 2017-18 Budget, $6.8 billion was invested in PBS listings, with generated savings from biosimilar medicines in the order of $600 million. Ms Shakespeare also emphasised the importance of price disclosure arrangements and statutory price reductions as they improve the Government's capacity to fund expanded access to biological medicines as they become more affordable.

Statutory price reductions: On the listing of the first new brand (generic or biosimilar medicine), the price that the PBS subsidises immediately reduces by up to 25% for both

Ms Shakespeare expanded on price disclosure arrangements, a mechanism that allows the Department of Health to accurately track what is happening in the market and enable cost reductions for the PBS to take place:

"We look at the prices at which medicines that are listed on the PBS are actually being sold in the market (where there's more than one brand). If there's a discrepancy between what the PBS funds and what the price in the market is then we reduce the PBS price down to what is happening in the market. This happens twice a year on the first of April and then again first of October".

Ms Shakespeare emphasised the success of these polices by presenting the observed price reductions for biological medicines following the introduction of biosimilar medicines:

- Infliximab: 44% price reduction since 2017
- Filgrastim: 75% price reduction since 2014
- Etanercept: 37% price reduction since 2017

Dr Marabani queried whether price disclosure mechanisms would be enough if there was very little movement or uptake of biosimilar brands for a particular biological medicine. In response Ms Shakespeare noted that price disclosure is affected by the actions of the market:

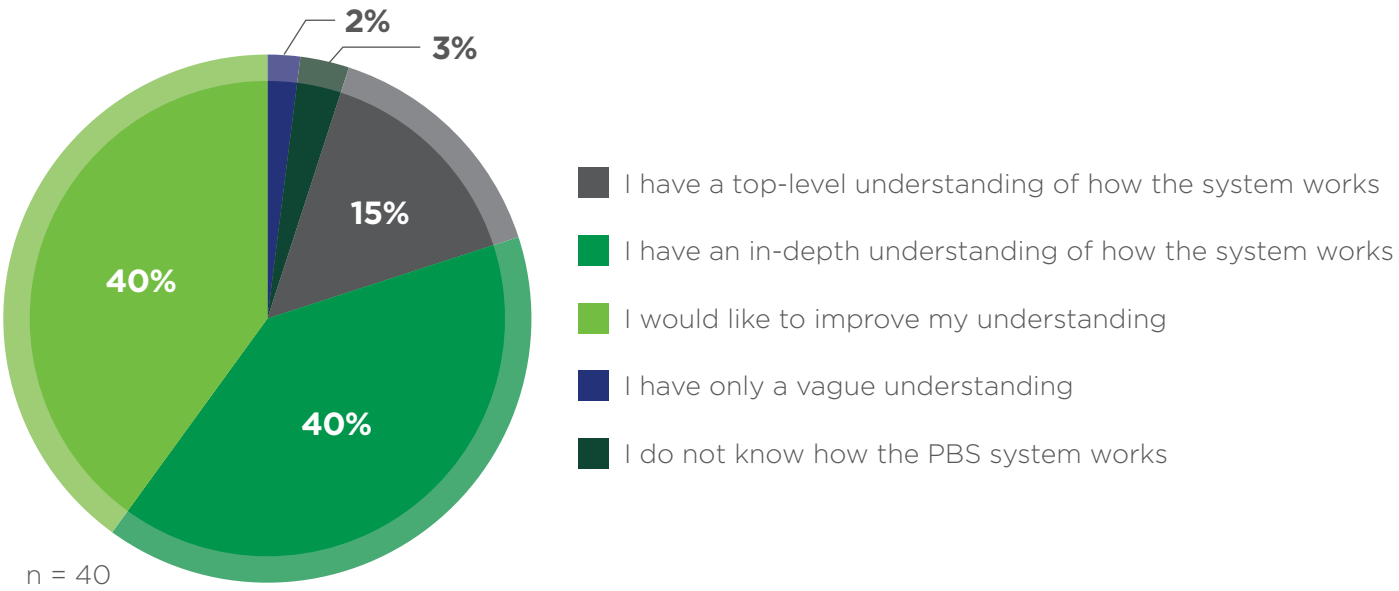
"Price disclosure works by following market behaviour. Market behaviour isn't necessarily always rational".

"There is a lot of switching going on and doctors using this brand rather than that brand. There is the anticipation of people wanting to protect their market share which is why even with fairly small uptake for some of our a-flagged biosimilars we've still seen some fairly significant price reductions through price disclosure"

Health Economics & Sustainability of the PBS

Of note, audience polling showed that 40% of respondents would like to improve their understanding of how the PBS system works:

Please select the answer that most closely resembles your understanding of the Pharmaceutical Benefits Scheme (PBS) in Australia?



"I think it's important to have that conversation [about the PBS pricing model] because as a clinician if you'd asked me about price disclosure five years ago, I wouldn't have known anything about it. Therefore, I suspect the majority of people who prescribe these drugs don't know." — Dr Marabani

"Further competition reduces the price within the marketplace. And that can only come from continued prescribing and I guess making the Australian market attractive for manufacturers of these products to bring to market."— David Ford

Following audience discussion, it was suggested that education on the PBS was needed for healthcare professionals to better understand how biosimilar medicines can contribute to the sustainability of the healthcare system.

Excerpts from workshop guides for reference:

A competitive market supports the sustainability of the PBS

Formulary 1 (F1) includes medicines protected by patent (single listed brand). Drugs listed on F1 are subject to statutory price reductions on the fifth, tenth, and fifteenth year anniversary of the date that the drug was listed on the PBS.

Formulary 2 (F2) includes medicines subject to competition (multiple brands available).[1]

When the first competitor brand becomes available (Figure 1, Step 1), the originator brand moves from F1 to F2, undergoes a statutory 25% price reduction (Step 2) and is subject to Price Disclosure (Step 3).[2]

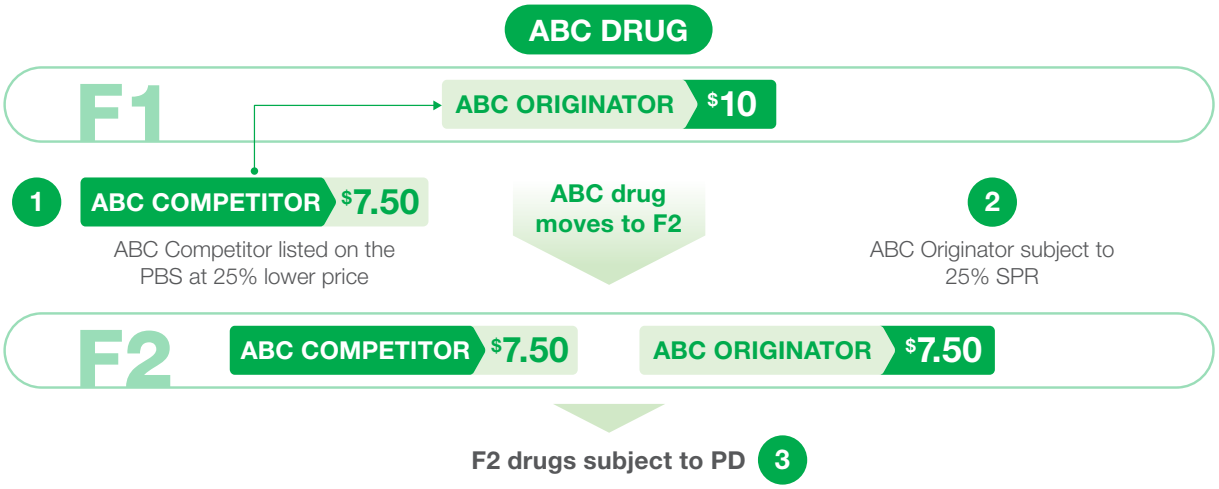


Figure 1. Transition of brands through the PBS. Adapted from Australian Government - Department of Health. *PBS Pricing Forum*, December 2018.[2]

PD, price disclosure; **PBS,** Pharmaceutical Benefits Scheme; **SPR,** statutory price reduction.

Price disclosure helps to ensure the subsidy for PBS medicines **reflects the average price** in the market. All medicines* listed on the F2 formulary are subject to price disclosure whereby all manufacturers of affected products must disclose sales volume and revenue data every six months to the Price Disclosure Data Administrator (PDDA). The PDDA calculates weighted averages for disclosed prices and compares them to the current PBS ex-manufacturer price for brands of each pharmaceutical item. If a price difference of 10% or more is found (or 30% or more for medicines that have been subject to price disclosure for 42 months or more), then a price reduction will occur on the next price reduction day (reduction days occur on 1 April and 1 October each year).[3]

*Some exemptions apply.

Attendees queried whether biosimilar medicines were used more in hospital or the community setting. Ms Shakespeare noted that while most biological medicines were being prescribed in hospitals at present, that with insulin glargine now listed with a biosimilar and many other medicines soon to come off patent, there will be an increase in biological medicines that will be dispensed in the community.

Increasing use of biosimilar medicines to support PBS sustainability

Feedback from the audience was that the key motivation for healthcare professionals was better patient care and outcomes. Cost reductions from biosimilar medicine use were viewed mainly as a potential mechanism to enhance supportive care such as additional nurse, pharmacist or administrative support time.

One specialist in attendance suggested revision of the "5 strikes rule" as an additional uptake driver to increase the prescription of biosimilar medicines noting that under current regulations patients are entitled to five PBS subsidised medicines for a condition throughout their lifetime:

"One [uptake driver] I've always thought would be nice would be if you used a biosimilar you got a sixth strike instead of five." [specialist]

With regards to uptake of biosimilar usage, concerns were raised about multiple switching, particularly in the community pharmacy setting, with attendees querying whether this would lead to confusion with differences between injecting devices.

Ms Shakespeare noted that these kinds of questions are taken into account by the Pharmaceutical Benefits Advisory Committee (PBAC) when considering whether or not to recommend an 'a-flag', adding that the Government is advised by medicines experts who are mindful of clinical aspects such as possible patient confusion. To which David Ford suggested:

"If a clinician doesn't want anything to be switched, then tick the [brand substitution not allowed] box, so it can't be switched".

Questions were raised about who should take ownership of patient education, to support uptake, with discussions centring on two possibilities:

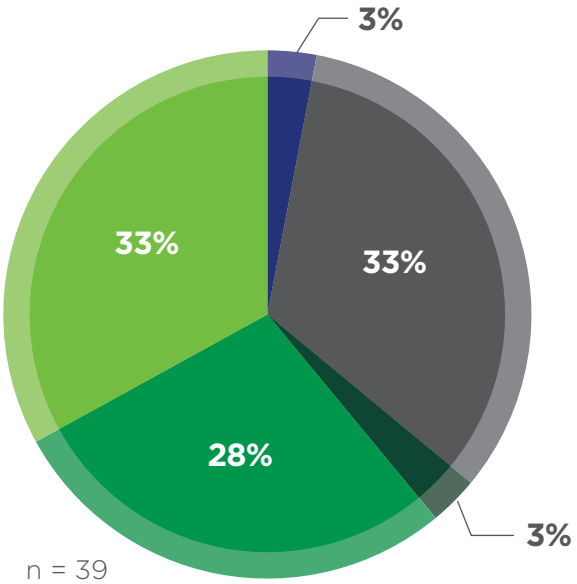
- Funding of community pharmacists to train and counsel patients:
  - Attendees noted that pharmacists are the most highly accessible health profession, and highly trusted in the communities;
  - Ms Shakespeare noted that the Commonwealth Government has community pharmacy agreements that get negotiated every five years and this includes funding to community pharmacies for not only dispensing, but also clinical programs that support dispensing.

- Nurses in private practice, with remuneration provided for placement in specialist practices to train patients.

It was acknowledged that there is a duty of care for all healthcare professionals to ensure that patients know how to use their devices.

When polled, the majority of respondents (94%) indicated they are comfortable with the use of biosimilar medicines, with 33% of whom indicating that concern remains around multiple switching:

Please select the answer(s) that most closely resemble your thoughts on biosimilar medicines.



Ms Shakespeare closed the discussions by reinforcing the benefits of the PBS in Australia:

"The PBS is a fantastic policy creation; it gives people maximum choice and maximum access to the full range of medicines that companies are willing to bring to Australia and we want to preserve it. We want to use the system as best we can to continue to drive sustainable prices so we can invest in new medicines".

Track and Traceability, and Pharmacovigilance

Adj. Prof. John Skerritt
Deputy Secretary for Health Products Regulation, Department of Health
CHAIR

Prof. Stephen Clarke
Medical oncologist at the Northern Cancer Institute and Royal North Shore Hospital

A/Prof. Simone Strasser
President of the Gastroenterological Society of Australia

A/Prof. Michael Ward
Discipline Leader: Pharmacy Education, School of Pharmacy and Medical Sciences, University of South Australia

Adj. Prof. John Skerritt opened the workshop by explaining the Therapeutic Goods Administration's (TGA) role in biosimilar medicine regulation to ensure there is a high degree of confidence that a biosimilar medicine is similar enough to the originator molecule, through thorough assessment of the molecule in both the evaluation process and post-market reporting.

Adj. Prof. Skerritt also highlighted the importance of manufacturing practices in the production of biosimilar medicines, noting that the TGA inspects facilities either in person, or via documentation, if the facility has already been inspected by a comparable regulatory agency, such as the TGA's Canadian or German counterparts. The TGA will send qualified inspectors to read all the production documentation and inspect the physical systems of the facility, with the key assessment focussing on whether the manufacturing processes that have been put in place will be able to produce the same product consistently. Adj. Prof. Skerritt pointed out that the manufacturing facilities required to produce biological medicines are worth hundreds of millions of dollars.

"You're not going to be sinking that sort of capital into a facility and then cut corners – the level of compliance is very high."

An audience member queried whether it was possible for biosimilar manufacturers to have different processes for manufacturing, compared to the originator brand. Adj. Prof. Skerritt confirmed that this is possible, clarifying that while there are differences and proprietary tweaks about how the molecule is made, the end result has produced a product that is highly similar to the originator product and is highly reproducible – something that applies to both the originator and biosimilar brands.

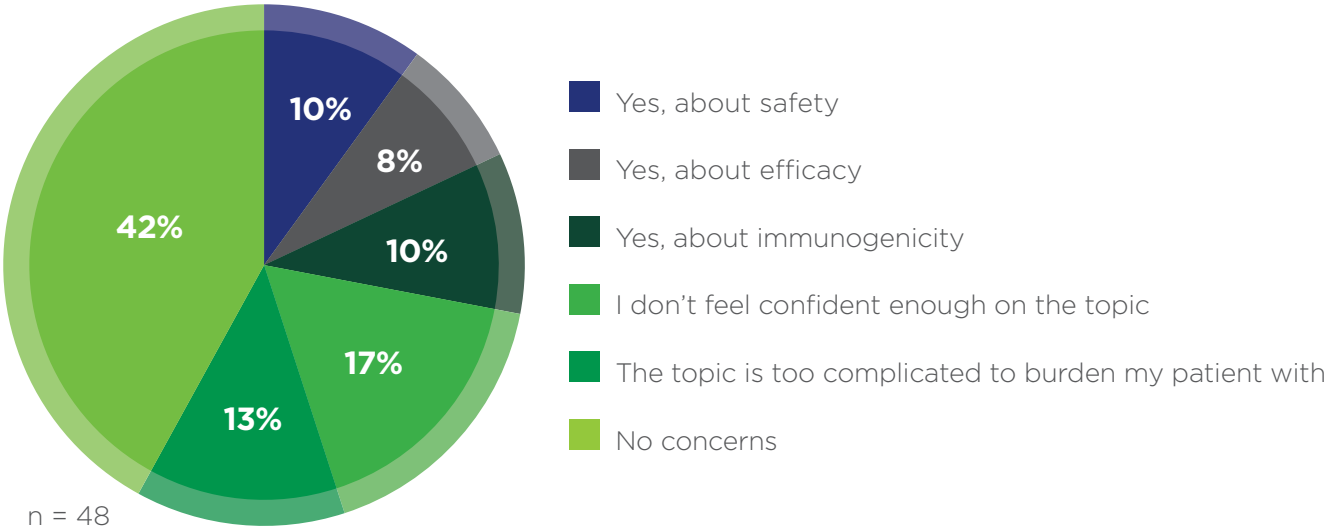
"Both [the originator and biosimilar brands] are monitored with the same level of rigour to ensure that each batch is consistent within a very controlled window of parameters."

A/Prof Michael Ward added that the evaluation process for a biosimilar medicine is on the end product, not the process of how you get there, noting that there are multiple ways to arrive at the same endpoint.

Safety of biosimilar medicines

When polled, a total of 28% of respondents indicated they have concerns about the efficacy, safety and/or immunogenicity of biosimilar medicines.

Do you have any concerns about the use of biosimilar medicines?



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Dr Stephen Clarke, oncologist, suggested that concerns may arise about safety when dealing with conditions or treatments where there is no immediate pharmacodynamic endpoint, such as drugs in cancer. He compared this to the use of erythropoietin, whereby if the patient's haemoglobin increases you can quickly see that the treatment is effective.

One audience member commented that their concerns stem mainly from the context of biosimilar medicine use, noting that even if you agree that biosimilar medicines are efficacious and safe you cannot know for certain the circumstances of their use. A/Prof Ward acknowledged that it's important to understand the fundamental science behind, and the evaluation process for, biosimilar medicines. He added that through highly sophisticated analytical techniques, we are able to detect anti-drug antibodies binding to different batches of both originator and biosimilar products and so far, the binding is indistinguishable suggesting that the concerns around immunogenicity and biosimilar medicines is not substantiated by evidence.

Dr Clarke, who has previously been involved in TGA sub-committees, also pointed out that once he understood the evaluation processes undertaken to assess biosimilar medicines, he was reassured about their use:

"Having seen the processes, knowing what they [biosimilar medicines] have to go through to get registration, I was reassured that we're on the right path."

Tracking & traceability

During Adj. Prof. Skerritt's opening address he commented that a couple of countries around the world, such as the USA and Japan, had made the choice to attach a suffix to the end of the non-proprietary drug names, to allow for tracking of brands. However, Adj. Prof. Skerritt noted that it was a Government decision, that if you are trying to encourage meaningful interchangeability, then the use of a suffix can become a barrier for substitution. As such, in Australia, a product's trade name, as well as the non-proprietary name, was made a mandatory field when reporting adverse events, in order to provide product specificity.

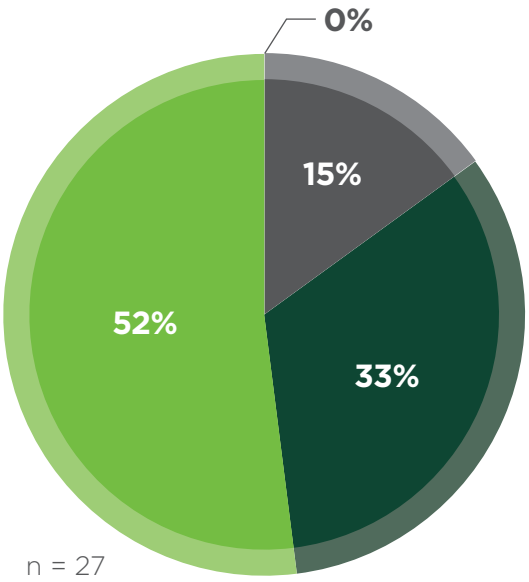
In addition, Adj. Prof. Skerritt announced that there will be a requirement for traceability of medicines under new labelling orders for all prescription medicines as of September 2020. These new mandatory requirements include a machine-readable code on the prescription packaging to identify different product variants, strengths, pack sizes and dose forms.

Adj. Prof. Skerritt also highlighted that the TGA is currently considering a voluntary standard for 2D barcodes which would enable tracking of individual batches of products.

Pharmacovigilance

When polled, only 33% of respondents noted they were comfortable with the pharmacovigilance system in Australia.

What are your views about pharmacovigilance activities in Australia?



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- I'm comfortable with the processes that the TGA has in place
- I'm concerned about underreported adverse events due to the voluntary system
- I'm confident in the system but would like visibility on dispensed brands
- I am not familiar with how the pharmacovigilance system in Australia works

International experience

Adj. Prof. Skerritt also presented on a set of joint statements agreed by the International Coalition of Medicines Regulation Authorities (ICMRA), comprised of the heads of 29 regulatory authorities from around the world, about confidence in biosimilar medicine products:[4]

Regulators have a role in enhancing prescriber and patient confidence[5]

- Manufactured to the same rigourous standards as other biologicals
- Approval after rigourous evaluation of similarity by regulators
- Demonstration of high similarity to an already marketed originator
- Full clinical development program is not necessary, just comparative pharmacokinetic and clinical studies for most sensitive indication
- Global confidence in the regulatory process for biosimilars
- Long history of safe use and pharmacovigilance systems robust
- Biosimilars enhance competition in biological medicines
- Biosimilars have been increasingly used in clinical practice - deepening experience in switching between products.

ICMRA Statement, July 2019

Adj. Prof. Skerritt also pointed out that while there are different viewpoints globally about biosimilar medicines, work is being done to more closely align regulatory standards and practices from a global standpoint.

Patient-centric Care and the 'Human Factor'

A/Prof. Andrew Miller
Immediate Past President of the Australasian College of Dermatologists

Dr Harry Nespolon
President Royal Australian College of General Practitioners

Dr Simon Ghaly
Head of the Inflammatory Bowel Disease Service and Staff Specialist at St. Vincent's Hospital and patient representative

Yen Shih
Patient representative
Crohn's disease

A/Prof Andrew Miller opened the workshop discussion by highlighting the critical importance of patient understanding and involvement in their own healthcare to ensure patients have a clear expectation of their treatment options and possible outcomes. A/Prof Miller went on to discuss the importance of understanding where patients seek health information. A/Prof Miller noted that – as specialists can be difficult to contact – GPs and pharmacists are often patients to discuss their experiences, raise concerns and request advice.

Dr Harry Nespolon, RACGP President, noted that discussions with patients are all about trust and clear communication:

"Patients who are unhappy, undecided or who aren't clear about the treatment prescribed by their specialist often come to GPs and ask, 'Should I be doing this?'."

A/Prof Miller stressed that consistency in patient communication between healthcare professionals is vital, noting that:

"If patients start to doubt their therapy this can introduce risk."

Yen Shih, a patient representative who was switched from originator infliximab to biosimilar infliximab in 2017, noted that his concerns focused around efficacy and whether there would be any side effects:

"From the patient perspective, we need to understand what it's about, why we're doing it and whether it is safe for us."

Dr Simon Ghaly, gastroenterologist and lead investigator for the SAME switch study at St Vincent's hospital, noted that the use of biosimilar medicines in his hospital has helped to support better patient care:

"The incentive for us was to try and leverage additional support within our unit – nursing staff time or admin time to reinvest [savings] into patient care so that there would be a direct benefit to the patients if we were going to change a treatment."

Dr Ghaly recommended that patients' baseline symptoms and personalities be taken into account when considering whether to switch to a biosimilar medicine, noting that, in his experience, baseline symptoms often correlate with how likely patients are to have other non-specific symptoms unrelated to the drug.

Dr Nespolon added that the communication from specialists to GPs and/or pharmacists needs to be clear about the treatment rationale and, if any changes have been made, to ensure that the nocebo effect is minimised. He highlighted that patients 'don't like surprises' and this would help reduce confusion as they move from their specialist to their GP and pharmacist.

A nocebo effect is defined as 'a negative effect of a pharmacological or non-pharmacological medical treatment that is induced by a patient's expectations, and that is unrelated to the physiological action of the treatment (both in a clinical and routine care setting)'

Dr Ghaly shared his experience with the nocebo effect in his practice:

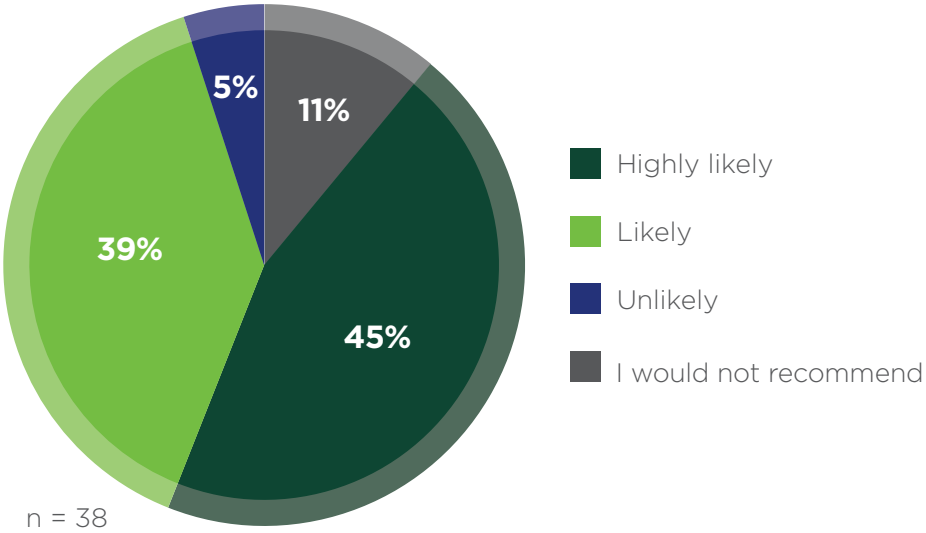
"We had a patient in our control arm [of the SAME study] who remained on the originator but came complaining that everything had gone pear shaped. As soon as I said that we haven't actually changed his brand, all the complaints went away, and we never heard about them again."

A/Prof Miller highlighted the importance of patient education and consultation to ensure patients understand the proper technique for using their medications. Noting that the downstream effect of this could increase the risk of patients failing therapy – not because the drug didn't work – but because the patients didn't understand how to use it, which can result in technical breaches to their program and loss of access to their biological treatment. This concern was shared by those working in the public hospital setting, noting that they often deal with huge volumes of patients and may have insufficient resources to adequately cover device training.

Patient-centric Care and the 'Human Factor'

When polled, 84% of respondents reported they were either likely or highly likely to recommend a biosimilar medicine:

How likely are you to recommend a biosimilar medicine to your patient?



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Pharmacy incentives

Attendees raised concerns around pharmacy incentives to switch patients to biosimilar medicines and how this would be regulated to prevent multiple switching of brands. It was highlighted that – unlike many small-molecule generic medicines – stock volumes for biological medicines are low due to cost, limited fridge capacity etc., meaning the incentive for pharmacies to stock multiple brands is minimal.

Information needs of patients

A common query was whether there is a need to delve into the specifics about biosimilar medicines with patients, noting that too much information might confuse patients and make them doubt their treatments. Dr Ghaly suggested that:

> *"What you put to the patient should be only what you think is going to be clinically relevant."*

The choice of brand used in hospitals is based on decisions made by the clinician-led therapeutic advisory group and as such, it was noted that use of biosimilar medicines is now commonplace in many hospitals. One attendee shared that they did not discuss whether a brand was an originator or biosimilar, as in their view, the medications were the same.

Conclusion

The *Your Patients, Your Government* Multidisciplinary Forum and Workshop generated constructive discussions between the healthcare sector and Government concerning biosimilar medicines. The event has led to valuable insights on future activities to support the uptake of biosimilar medicines under the Education Grant, and beyond.

Furthermore, attendee feedback was consistently positive indicating a high level of stakeholder engagement with the issues raised in the workshop discussions. In particular, the importance of improved communication channels between healthcare stakeholders surrounding biosimilar medicines was seen as essential to address the barriers to biosimilar medicines uptake in Australia. The audience therefore considered healthcare professionals to be critical channels of information for patients, to help support confidence in biosimilar medicine use.

Insights gathered from this workshop will be utilised by GBMA Education to further develop and build upon the strategy and focus across each healthcare profession for the Biosimilar Education Grant Program. This year, the focus will shift to include consumers and carers which means that it is vital that an appropriate communication strategy is employed with healthcare professionals to ensure that they are aware and able to answer any queries that may come through from consumers/patients about biosimilar medicines.

Biosimilar Education Grant

GBMA Education is the educational arm of the Generic and Biosimilar Medicines Association and is responsible for the delivery of educational, fact-based information for biosimilar medicines through a Government-funded grant.

The Biosimilar Education grant opportunity aims to increase confidence in the use of biosimilar brands of biological medicines that are listed on the Pharmaceutical Benefits Scheme (PBS). The program objective is to support a competitive market for biological medicines via peer-to-peer health communication activities that support the increased use of biosimilar medicines, and as a result provide:

- Cost savings can improve the Government's capacity to fund expanded access to biological medicines as they become more affordable. The savings will flow from market competition on price, and related reductions in the PBS subsidised price under the PBS price disclosure arrangements;
- Protect against medicines shortages, which are an increasing issue worldwide; and
- Increase prescriber and consumer choice.

Feedback

Should you wish to discuss any aspect of the multidisciplinary workshop further, please contact admin@gbmaeducation.com.au.

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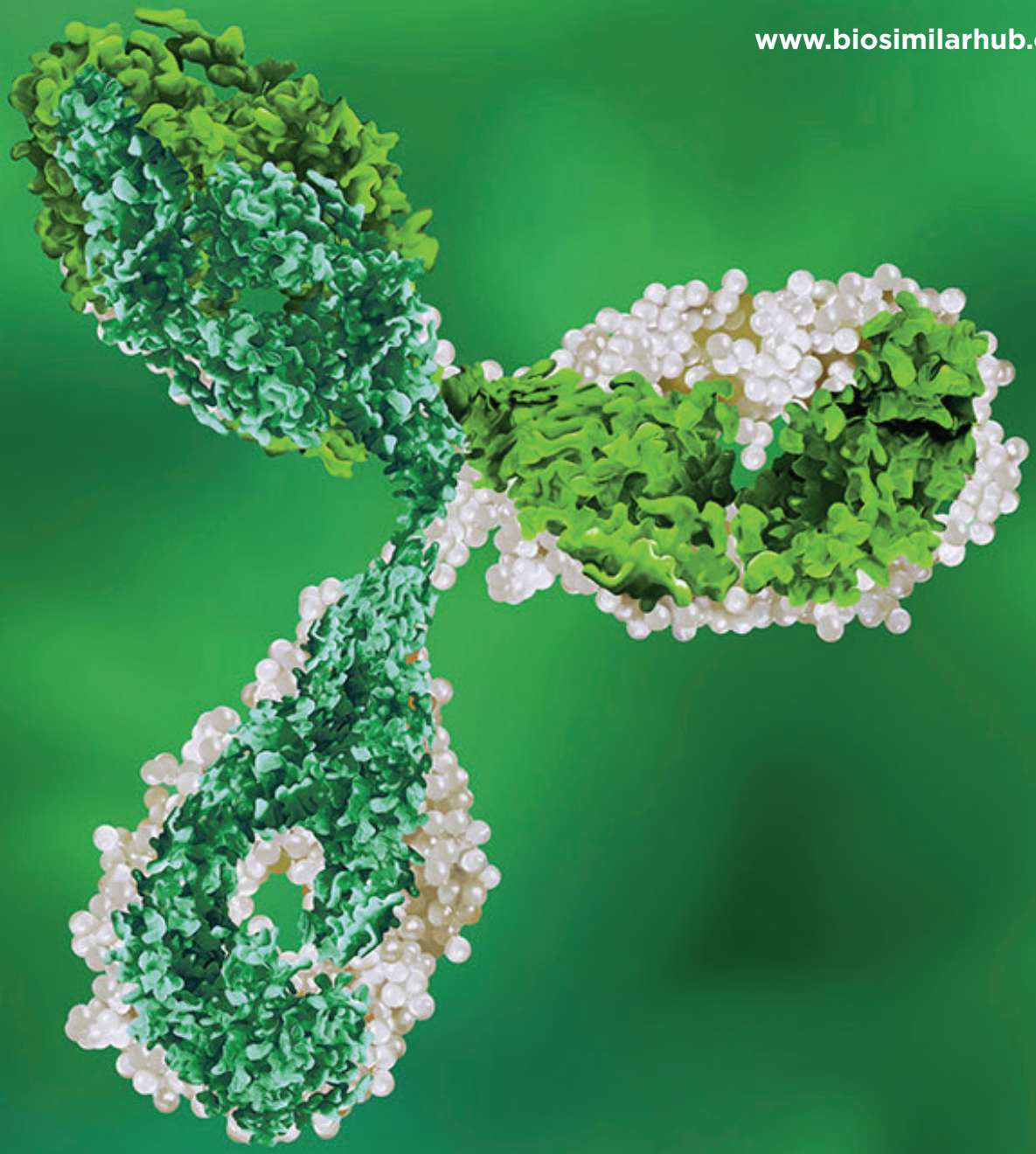

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