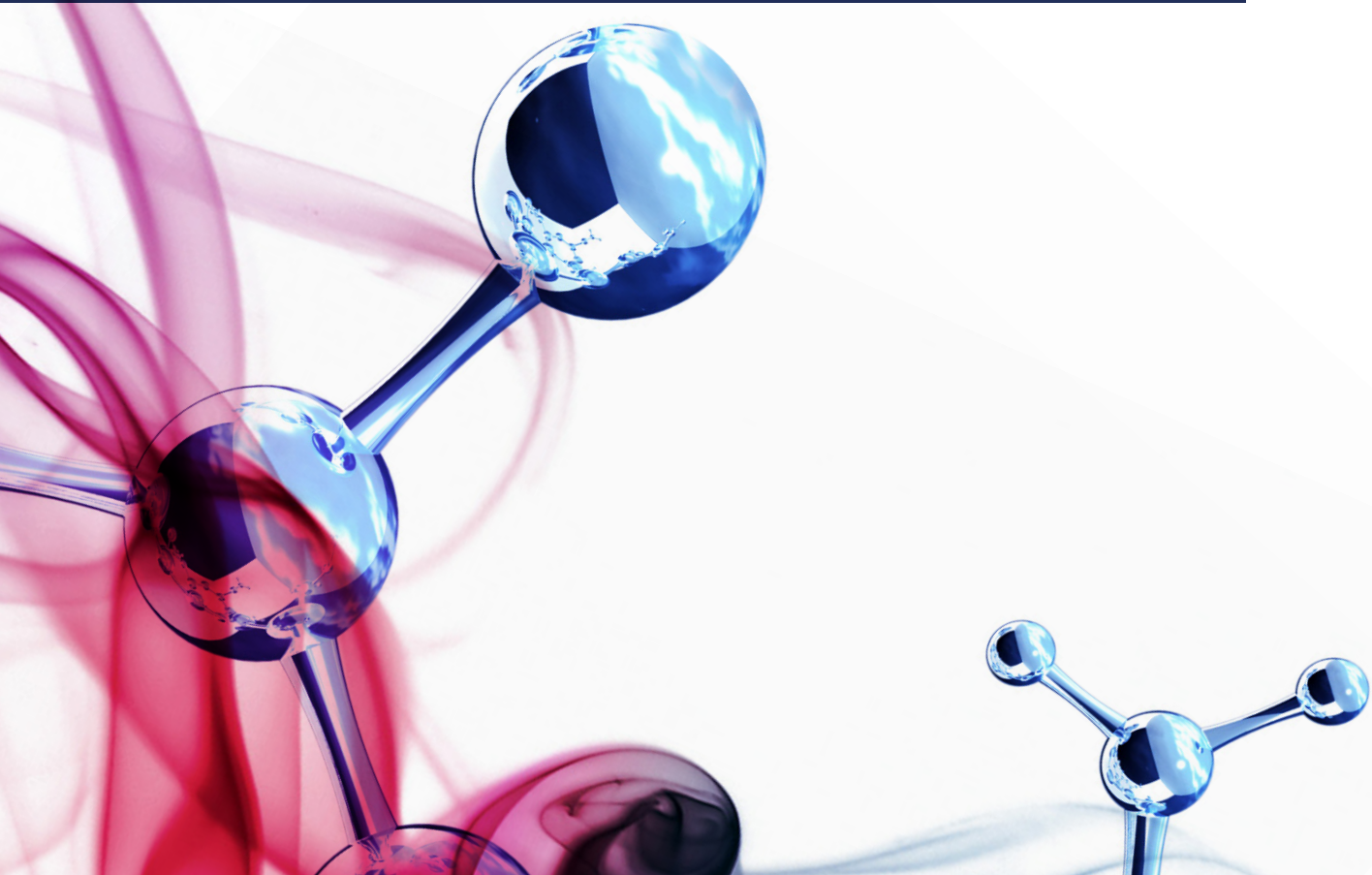
REPORT 2016

BIOLOGIC AND BIOSIMILAR MEDICINES 2020: MAKING THE MOST OF THE OPPORTUNITIES



This report captures multi-stakeholder perspectives on the opportunities afforded by biologic and biosimilar medicines in Australia and the key steps required to advance the evolving framework for the introduction and use of these medicines, in alignment with the National Medicines Policy.

Organising Committee

AusBiotech
Consumers Health Forum of Australia
Council of Australian Therapeutic Goods Advisory Group
Medicines Australia
NPS MedicineWise
The Pharmacy Guild of Australia
The Royal Australasian College of Physicians
The Society of Hospital Pharmacists of Australia

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FOREWORD

The availability of both biologic and biosimilar medicines has the potential to make a significant positive impact on the Australian healthcare system. *The Biologic and Biosimilar Medicines 2020 Forum* held on the 23 June, 2016 in Sydney, brought together a broad range of representatives of the Australian healthcare industry to discuss the many opportunities and new and unique challenges the availability of both biologic and biosimilar medicines present.

The Forum included health professional, consumer, patient advocacy group, medicines industry, and policy and regulatory representation, all sharing their particular views and experience in the use of biologic and biosimilar medicines.

While Australia has taken a number of important first steps, there was an acknowledged need to bring the broad range of stakeholders together in this way to gain new insights, discuss the current framework, and future opportunities and challenges of these medicines to enable their success.

The Forum's organising committee wish to thank the more than 80 contributing attendees. While there were a range of commonalities discussed throughout the Forum, the broad range of perspectives demonstrate the extensive opportunities and intricate challenges facing all stakeholders involved in this complex and evolving field that require further consideration and focus.

The Forum cemented that we must as ever, remain patient-focused, driven to improving patient outcomes. It is hoped the Forum's discussions, and issues identified will complement and enhance existing and future initiatives to ensure the success of biologics and biosimilars to the benefit of Australian patients and their families.

Feedback from discussions on the day indicated an impetus to continue to jointly progress the issues raised beyond the Forum, and we hope this collaborative approach will enable the health community to continue to benefit from the opportunities biosimilars present, now and in the future.

Organising committee:

The Pharmacy Guild of Australia

CHF Consumers Health Forum of Australia

RACP Specialists. Together
EDUCATE. ADVOCATE. INNOVATE

NPS MEDICINEWISE

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Council of Australian Therapeutic Advisory Groups

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The Society of Hospital Pharmacists of Australia

MEDICINES Australia

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EXECUTIVE SUMMARY

A number of important steps have commenced in Australia to ensure our health community can begin to embrace the true potential afforded by biologic and biosimilar medicines. Within this context, more than 80 stakeholders gathered for *The Biologic and Biosimilar Medicines 2020 Forum* in Sydney on 23 June 2016, to maximise the opportunities these medicines present to the Australian healthcare system now and in the future. The Australian National Medicines Policy provided a framework for the Forum to discuss the opportunities and challenges presented by the availability of both biologic and biosimilar medicines in the coming years.

A broad range of perspectives were considered throughout the Forum from across the medicine and patient journey including research, industry, Government, medical, pharmacy and consumer. The expanding number of settings in which biologic and biosimilar medicines may be used was also taken into consideration including hospitals, specialist medical centres, primary care, community pharmacy and non-clinical environments such as the home.

Forum structure

The Forum commenced with a series of presentations, showcasing the perspectives and considerations that consumers, specialist prescribers, hospital formulary decision-makers, community pharmacists and the medicines industry may have regarding the current and potential future use of biologic and biosimilar medicines. These presentations identified significant common ground and a shared willingness to embrace the opportunities and address the challenges. Following this, delegates attended two of four workshops based on the four pillars of the National Medicines Policy:

1. Timely access to the medicines that Australians need, at a cost individuals and the community can afford
2. Medicines meeting appropriate standards of quality, safety and efficacy
3. Quality use of medicines and
4. Maintaining a responsible and viable medicines industry.

The current context

The Forum was intended to complement other existing and emerging initiatives and policies in this area, with all discussions underpinned with the acknowledgement that Australia has the core framework and systems in place to support the availability, uptake and use of biologic and biosimilar medicines. It was acknowledged that there are frameworks and processes in place to support access to medicines including the National Medicines Policy, and that regulatory and reimbursement processes may naturally evolve over time as more biologic and biosimilars medicines come to market.

Vital to supporting the successful uptake and use of these medicines in Australia is the Federal Government's $20 million *Biosimilars Awareness Initiative*. However, with the increasing number of biologic and biosimilar medicines due to be introduced in the next decade to the Australian healthcare system, there are a number of key aspects requiring further consideration to ensure the healthcare system is best equipped to provide Australians with greater and more affordable access to these therapies.

Core themes

The Forum's discussions identified a number of key aspects which were felt to warrant further consideration. Many of these are interlinked and interdependent, so are therefore able to be grouped into four core themes.

1. Improving the evidence base

To support the evolving biologic and biosimilars market and to improve patient confidence in these treatments, the need to improve the evidence base was identified and included the following considerations:

- Ensuring an effective and systematic approach to collecting data on the use of biologic and biosimilar medicines across different care settings is embedded into clinical practice and workflow. This includes the use of existing data collection systems (e.g. DAEN and specific registries) and eHealth records
- Improving the evidence base to better inform regulatory and reimbursement decision-making
- Improving the evidence base to better understand potential impact on disease/symptom control, immunogenicity and adverse events
- Increasing the evidence base through pre-market and prospective studies, in particular around switching and multiple switching, to ensure quality, safety and efficacy to strengthen prescriber, pharmacist and consumer confidence in these treatments.

2. **Optimising data capture**

Forum discussions repeatedly raised the benefits of a more patient-centred, comprehensive and efficient data collection system, in particular the opportunities made possible with the ability to access real-time data. Ideally, this data would be easily shareable and accessible to all members of the multidisciplinary healthcare team, the patient and their family/carers via an electronic platform, and would allow all members of the multidisciplinary healthcare team to access patient information in real-time. This would help inform all involved in an individual's treatment journey and support the team to provide consistent treatment recommendations.

The opportunity to develop a systematic, electronic process for capturing prescribing, dispensing and post-market patient centred data was also identified. This could be achieved through leveraging the highly engaged healthcare professionals, patients and industry bodies to collect and share data, developing a more comprehensive data collection and analysis that will improve and support decision-making at all stages - from registration and reimbursement, to prescribing and dispensing. In addition, the need for further clarity around data requirements and access was identified as an area of focus.

3. **Pharmacovigilance and naming conventions**

Developing more comprehensive up-to date pharmacovigilance systems and reporting processes for biologic and biosimilar medicines was a consistent theme throughout the Forum discussions. It was noted that this relies, in large part, upon clarifying naming conventions and ensuring they are appropriate. Key considerations included:

- Expanding pharmacovigilance to incorporate the consumer and clinical perspectives of acceptable quality, safety and efficacy of biologic and biosimilar treatments particularly in relation to 'acceptable' responses and what adverse effects may be deemed to be most troublesome
- Developing a more comprehensive, collaborative and systematic pharmacovigilance system that captures changes of therapy where relevant and determines how and when changes in response to different biologic and biosimilar treatments may occur. This would lead to more effective management of issues associated with the use of these medicines
- Developing clarity around naming conventions for biologic and biosimilar medicines, as how this is addressed will improve traceability and confidence in switching.

4. **Building stakeholder confidence and shared decision-making through high quality information**

Confidence was noted as a key factor in ensuring increased uptake of biosimilars. Central to improving consumer and healthcare practitioner confidence, understanding and awareness of biologic and biosimilar medicines will be the availability of consistent, up-to-date, comprehensive, responsive and user-friendly information developed by an independent credible source.

Every individual's treatment journey with a biologic or biosimilar medicine is unique, and everyone involved in the treatment pathway needs to have confidence in the available information to make well-informed and shared decisions. This includes resources that are tailored to the information needs and level of health literacy of the individual, and may need to be specific to a particular medicine or brand, rather than health condition.

The discussions identified the development of a central access point to distribute this information could decrease the likelihood of mixed messages and inconsistencies in currently available information. As there are many stakeholders with a variety of needs and perspectives, providing comprehensive impartial information will be critical.

The development of tailored and practical education resources and tools may also be beneficial in minimising mixed messages and supporting shared decision making. For example, a universal Q&A for both clinicians and consumers has the potential to support consumers seeking information independently, as well as serve as a guide for clinicians' discussions with patients about these medicines.

It was noted that the Government's *Biosimilars Awareness Initiative* will be critical in building confidence by meeting education and information needs.

Where to next?

It is hoped this report's prospective view and key themes and issues outlined in the following pages will support the Australian healthcare community in realising the significant opportunities provided by biologic and biosimilar medicines now and in the future. These include the potential for better health outcomes for consumers living with serious health conditions, the potential for more treatment options in Australia, and the potential to realise future cost savings for the health care system.

Key to addressing these themes will be to continue to work in collaboration with all involved stakeholders, to complement current initiatives such as the Government's *Biosimilars Awareness Initiative*, and to identify new initiatives based on the themes identified throughout this report, that will address the current and future opportunities presented by biologic and biosimilar medicines.

If you would like to discuss the report in further detail, or would like to register your interest in staying involved as these issues are progressed, please contact a member organisation of the Steering Committee or direct your queries to forum@biosimilars2020.com.

PERSPECTIVES

The first part of the forum was dedicated to hearing from a broad range of representatives across the healthcare community, from consumer, prescriber and hospital setting, to pharmacy and medicines industry. Representatives shared their unique perspectives and insights into their experiences with biologic and biosimilars medicines, as well as what they identify as the key challenges and opportunities these medicines present for the current and future Australian healthcare system and its patients.

THE CURRENT LANDSCAPE OF BIOSIMILARS IN AUSTRALIA

Ms Kerren Hosking, Executive Manager, Corporate Affairs and Governance, NPS MedicineWise

Biologic medicines are considerably more complex than chemically synthesized medicines. Even the simplest biologics are highly purified protein products, consisting of more than one molecular entity - usually mixtures of many closely related molecular species.

Biosimilars are not identical versions of off-patent innovator biologics, but they have the same kind of DNA sequence. Biosimilars need to have demonstrable similarity of physiochemical, biological and immunological characteristics to the reference biologic, and safety and efficacy based on comprehensive comparability studies.

Medicines of this nature are sensitive to slight changes to manufacturing processes which can't be replicated exactly and this applies to different batches of biologics along with biosimilar medicines. The TGA has implemented a rigorous approval pathway for biologic and biosimilar medicines, and these are regulated to very high standards.

There are ongoing discussions regarding pharmacovigilance systems, optimising data capture and adverse event reporting for biologics and biosimilars. One consideration is the implementation of a consistent naming convention for biologic and biosimilar medicines. This is currently being developed by the World Health Organization, and is still under review and consideration within the Australian context.

Whilst biologics have been part of the medicines landscape in Australia and internationally for some time, these medicines are not well understood by consumers or healthcare professionals outside of certain professional specialties. This is a major barrier to the uptake of biosimilar medicines.

In 2015, the Government announced a commitment of $20 million over three years to improve the uptake of and confidence in biosimilar medicines. The main aims of this project are supporting use and awareness of biosimilars amongst both healthcare professionals and consumers, ensuring appropriate policies are in place to support market access, increasing consumer choice and achieving tax payer savings.

Recent research on attitudes towards biologics and biosimilars, commissioned by the Department of Health, indicated that there is low awareness of the PBS processes for listing treatments (including biosimilars) amongst consumers. Significant trust is therefore placed on the healthcare professional and their decision making regarding treatment. For healthcare professionals, any hesitations around prescribing and dispensing biosimilar medicines are largely fuelled by a lack of knowledge.[1]

Traditionally, biologic prescribing has been the domain of specialists, but their use is expanding in different settings. For example, primary care physicians are increasingly taking on the role of initiating treatment, along with patient management and monitoring. In addition, dispensing is increasingly happening through community pharmacies.

All of these factors provide us with opportunities to strengthen and enhance current systems, and it is important that we embrace them as we move forward. The major building blocks are in place to support the safe and effective use of these medicines. The key now is to understand the knowledge gaps, the information needs, the barriers to uptake, the gaps between evidence and practice, and how to address these in meaningful and appropriate ways across different settings and for different audiences.

[1] Further details of the research can be accessed at: www.pbs.gov.au/info/general/biosimilars

THE CONSUMER PERSPECTIVE

Ms Franca Marine, National Policy & Government Relations Manager, Arthritis Australia

Biologic therapies have transformed outcomes for people living with chronic inflammatory diseases, allowing people with these painful and debilitating conditions to have a chance to live independently, maintain social connections and employment, and improve their physical function, quality of life and reduce disability. They also reduce demands on the health and welfare systems.

Making effective biologic therapies more affordable via the introduction of biosimilar medicines is a very welcome development in the Australian market, however confidence regarding the safety, quality and effectiveness of treatment remains paramount. Many consumers are already concerned about the side effects of biologic medicines, and adding biosimilars into the mix adds another layer of concern.

There is a lack of available data on whether biologics and biosimilars can be used interchangeably. Switching and especially repeated switching between the biologic and biosimilar may increase the risk of an immune response and an adverse event, which is a major concern for consumers. Therapy failure can leave people without therapeutic options - a devastating outcome for someone living with their condition for a lifetime.

Achieving adequate disease control or remission for people living with chronic inflammatory diseases can be challenging, and the process can sometimes take years. Eligibility criteria for PBS-subsidised medicines are strict and require people to have failed on other therapies before a biologic can be prescribed. People who finally become stable on a biologic are very reluctant to make any changes that might put their disease control at risk.

Pharmacy level substitution opens consumers up to the possibility that they may inadvertently receive a different version of their treatment, and could even receive a different version each time they fill their script. Whilst there are safeguards in place to prevent this happening (such as the 'do not substitute' tick box on the script) these rely on the ideal scenario of an informed prescriber, informed consumer and informed pharmacist to work as intended. In the real world, human error or lack of awareness means there is no fail-safe protection against inadvertent substitution.

Pharmacy level substitution can also complicate safety and efficacy monitoring, and create confusion when reporting adverse events. Even if the product can be traced, it can take time for immunogenicity problems to become evident, making it difficult to identify which product caused any problems that may arise. With more than 30 biosimilars currently on the horizon, there is enormous potential for confusion among consumers and prescribers alike.

Until there is more evidence and consensus on interchangeability, any decision to switch a therapy should be a clinical one - agreed between the clinician and the consumer. To build confidence in the use of biosimilars, activities to increase awareness and understanding amongst consumers, prescribers and pharmacists are welcomed.

Clarifying the evidence base and criteria to support decisions around 'a' flagging is important, as is enhanced pharmacovigilance and adverse event monitoring to resolve current uncertainties such as the long term efficacy and safety of switching or substitution within the Australian environment.

A mother's perspective: Sarah McHarg's story

Until the age of 6, Sarah's son Patrick was an active, energetic and healthy child, when overnight his knees suddenly started to swell. Two months, several tests and a few surgeries later, Patrick was diagnosed with juvenile arthritis.

Over the first three years, Patrick progressively became sicker, frailer and as more limbs became affected, his mobility declined. "We used to lie in bed at night listening to him cry in his sleep in pain," Sarah recalls. "He lost a lot of weight, he stopped growing, and he missed months of school due to pain and joint stiffness. My husband and I had to make sacrifices at work to be there for him throughout the day."

"While once a happy and active child who used to bounce around with so much energy, he had to start relying on a walking frame and crutches to get around. At about nine years of age, we were looking at putting him in a wheelchair. The situation was not sustainable, and our stress levels were really high."

The family trialled many medications, which showed little to no improvement. Then, just as Patrick's condition became worse, Sarah was informed that he was eligible to receive a biologic medicine.

Sarah says getting access to the medicine wasn't an easy task, and she was sceptical at first – finding accurate and reliable information was difficult. "Initially I was really apprehensive about biologics. Like most patients, I did research and Google managed to scare the life out of me."

Luckily, however, Sarah found her rheumatologist and her pharmacist to be particularly helpful. "My pharmacist was a godsend, he provided me so much factual information and advice, and actually gave me the courage to try this different form of medication."

Coming in to receive his first biologic injection, Patrick was so immobilised that Sarah had to carry him into the surgery. But from that day, their lives started to turn around.

"Within days of that very first injection it was a miracle - his swelling started reducing, the mask of pain he wore constantly started to diminish. At 6 weeks, even his rheumatologist was surprised at how fast he had responded to the medication. He had little to no symptoms."

Five years on Patrick, now in high school, can enjoy playing his favourite sports. While he still experiences flare ups from his condition, the biologic has helped "take away the constant worry about joint damage or developing a disability."

"Parents and carers fear anything that might jeopardise improvement and maintenance of their child's condition," says Sarah, "so, the success and effectiveness of biologics in many ways makes us very vulnerable. Substitutions or access restrictions are very confronting."

For parents like Sarah with children suffering from devastating conditions, and for patients of any age - their imperative is to maintain the improvement in health and quality of life that a biologic medicine has afforded them, and that they have worked so hard to achieve. Fearing any change that might affect that progress, Sarah believes any medication changes or substitutions need to be made in direct consultation and with the permission of the patient.

THE PRESCRIBER PERSPECTIVE

Dr Mona Marabani, Immediate Past President, Australian Rheumatology Association
Associate Professor Susan Connor, Fellow, Gastroenterological Society of Australia

Biologic medicines have revolutionised the treatment of many conditions. Backed by an extensive body of evidence and post-marketing experience supporting their efficacy and a good understanding of toxicity, some have been available for over a decade.

Prescribers consider the patient's individual needs to determine what treatment will give the best outcome, whilst also being cognisant of the need to ensure value for the taxpayer from the healthcare spend. Prescribers are aware of the cost of biologic treatments and look forward to any innovations that reduce these costs.

It should be noted that only the most unwell patients qualify for biologic medicines, and detailed documentation needs to be filled out to apply for a PBS-listed biologic. Additionally many affected patients are young and thus the stakes are higher with respect to the importance of optimising disease control. In Australia, a patient is able to trial only a limited number of the available biologic medicines in their lifetime under current PBS prescribing criteria. There is no evidence to guide prescribers on what order the biologic treatments should be prescribed for any individual patient. It is also not possible to rely on a class-effect either, as some treatments have differential efficacy for different diseases, or patients may fail one treatment in the class and respond well to another. With this is mind, prescribers assess the individual needs of the patient to guide their decision making, and take into consideration differing circumstances - for example, if the patient is needle-phobic, if there are any adherence issues, if they are wanting to become pregnant, etc.

The key prescriber concerns regarding the increasing use of biologic and biosimilar medicines include:

- **Immunogenicity** – with potential for loss of efficacy or toxicity risks from multiple switching at the dispensary without prescriber knowledge.
- **Indication extrapolation** – current precedent is that one phase I study and one phase III study in another indication is sufficient for approval across all indications.
- **Lack of a non-proprietary naming convention for biosimilars** – which may cause issues with traceability.
- **Substitution without prescriber knowledge** – tracking which drug is responsible if there is a problem.

The first monoclonal antibody biosimilar approved for use in Australia was Inflectra (infliximab). On 1 December 2015, the PBAC determined that it should be given an 'a' flag, which means it is substitutable at the pharmacy.

Inflectra is an intravenous agent with a comfortable level of evidence for use in biologic naïve patients. Data shows one-way switching from the originator biologic to the biosimilar is safe and there are no safety signals, but follow-up periods are short and there is no data on multiple switching. It should also be noted that other available biologic disease-modifying drugs used in inflammatory arthropathies are administered subcutaneously, and biosimilars are becoming available for those too (e.g. etanercept). This could create confusion for patients if different syringes and delivery devices are available for different biosimilars.

As a whole, prescribers recognise that biosimilars present an opportunity for the health system. However, they are also conscious that there is a lack of data regarding these agents. To help build confidence amongst prescribers regarding biosimilars, to ensure these medicines are used safely and effectively, it is recommended that Australia:

- Commits to robust pharmacovigilance and surveillance
- Ensures better management of data that is already collected
- Understand that the clinician is driven by a duty to do what they think is in the best interest of their patient.

A PERSPECTIVE FROM THE HOSPITAL SETTING

Associate Professor Winston Liauw, Medical Oncologist, Clinical Pharmacologist and Chair of Drugs & Therapeutics Committee, St George Hospital

Associate Professor Liauw used the ***Council of Australian Therapeutic Advisory group, Overseeing biosimilar use: Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals, 2015*** *as a starting point for framing his perspective presentation, but also delved into a broader context beyond these principles, drawing on a range of influences and personal experiences to shape his considerations of biosimilars in the hospital setting.*

While the governance of biologic and biosimilar medicines in a hospital setting should be no different to any other medicines, it is important to be practical. Patients will come into hospital on biosimilars, and these medicines will need to be on the hospital formulary by necessity.

Like any other medicine, the choice to use a biologic or biosimilar as a first-line therapy should be guided by the available evidence to support the safety, efficacy and cost effectiveness of the medicine, which is determined by the TGA and PBAC.

When it comes to the prescription of a biologic or biosimilar, the active ingredient and brand name should be included on the prescription itself. However, consideration needs to be given to how this prescription is tracked following dispensing from the hospital pharmacy, and whether the appropriate technology is in place to support this.

A biologic should only be substituted with the prescriber's knowledge and consent. However in a hospital environment, there may be a scenario where the prescriber is unable to provide consent – in this case the hospital drug and therapeutics committee could provide approval and advice on the appropriate protocol.

Patients should be fully informed when receiving treatment with a biologic or biosimilar. To do so effectively, consideration should be given to the health literacy of the patient, as well as whether it is possible to sensibly inform patients if there is controversy.

If a product has been 'a' flagged by the PBAC there is no need for the hospital drug and therapeutics committee to make a subsequent ruling. Instead, it is important to educate patients and ensure the quality use of medicines to avoid confusion.

There should be a patient-centred pharmacovigilance framework within each hospital or health service to monitor and report outcomes and any adverse events associated with biologic and biosimilar therapies. Whilst this is definitely something that should be implemented, it is noted that there are areas for improvement in the current hospital and health service pharmacovigilance systems.

Fiscal concerns at a hospital level will drive the need to have procurement strategies to cover high cost, high volume biologics (e.g. EPO, filgrastim). Most issues will need to be resolved as a matter of pragmatism, but solving how to do effective pharmacovigilance for efficacy and safety is the real challenge. In addition, consideration should also be given to whether post-marketing trials of biosimilar medicines are needed.

THE COMMUNITY PHARMACY PERSPECTIVE

Mr George Tambassis, National President, The Pharmacy Guild of Australia

The primary focus of community pharmacists is to care for patients, and the patient's needs and wishes are central to the way community pharmacists operate. If a problem is identified, especially with a prescription, community pharmacists work with the patient and other relevant health professionals (most often the prescriber) to address the issue.

Pharmacies have been very successful in encouraging the uptake of generics, to the benefit of consumers, taxpayers, pharmacy viability and PBS sustainability.

Most pharmacies carry a very comprehensive range of generic medicines based on the pharmacy's dispensing history, and it is important for community pharmacists to know what prescribers in the local area are prescribing to ensure that they have appropriate stocks in place. Any substitution for a generic is done in consultation with the patient.

An increasing number of community pharmacies are becoming involved with highly specialised medicines such as biologics.

The approach to biosimilar substitution endorsed by The Pharmacy Guild of Australia is based on the appropriate, allowable substitution of biosimilars in compliance with the PBS listing and with the patient's well-being given uppermost importance.

The Guild has the confidence in the systems and processes in place with registration via the TGA and PBS listing for biologic medicines. Community pharmacists have confidence in the Australian process for substitution and are well placed to work with consumers to inform them and instill confidence in biosimilars. Substitution will only occur where it is allowed and where the pharmacist can be confident that the consumers can get the same therapeutic outcome.

Pharmacists generally have a good appreciation of the local prescribers' preferences with regards to substitution, because they work closely with their prescribers, including specialists and GPs. If issues are encountered, the pharmacist will consult the prescriber.

There are currently three trials underway to test automatic messaging from community pharmacy back to the prescriber to confirm when a medicine is dispensed. This is already happening for prescribers who have eRx on their software platform. The eHealth record will also help clear up any concerns regarding which brand of biologic or biosimilar a patient has been dispensed or if there is any substitution.

Lower cost biosimilars are beneficial for the sustainability of the healthcare system by reducing the PBS spend. When a new biosimilar comes onto the market, the price of the medicine comes down due to the price disclosure process.

Affordable biosimilars may lead to an increase in treatment options for consumers. To deliver the forecast savings from biosimilars, legislators may need to consider some form of incentives to prescribers, consumers and pharmacists to ensure the uptake target is reached.

Following signing of the agreement in 2015, the PBS savings identified from biosimilars is estimated to be $880 million over five years.[2] This could be used to introduce more medicines on to the PBS and potentially more biologics which will benefit taxpayers.

2. http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley063.htm

A MEDICINES INDUSTRY PERSPECTIVE

Mr Wes Cook, Chairman, Medicines Australia

Previously the focus around biosimilars has been on the areas where there are differences of opinion, but we believe we should focus on the areas where the stakeholders all agree. There is a common purpose amongst all the stakeholders in this room and that is a focus on putting patients first. Patient safety and health outcomes are a common goal amongst us all.

It is true that the introduction of biosimilars represents a unique opportunity for Australia to achieve savings (through competition in the off patent market) which Government can then reinvest in new and innovative medicines.

There are over 250 biosimilars being developed globally and medicines companies are looking locally to determine which countries to introduce them, how they will be introduced and what is the environment they will be entering. The ideal scenario is one where all stakeholders agree on how Australia should move forward to build a strong, evidence-based biologics and biosimilars sector. Biologics are presenting new treatment paradigms and new options, and we have to find ways to fund that in a sustainable way. Certainly the introduction of biosimilars does provide that opportunity.

There are many issues necessary to support the ongoing successful introduction of biosimilars for Australian patients. Whilst many of these are already being addressed, the Steering Committee representatives, including Medicines Australia, believe this Forum is an important opportunity to share views and ideas to compliment current initiatives and identify any gaps.

Medicines Australia is in the unique position of representing more than 50 manufacturers and sponsors of new medicines, including those companies who will also be responsible for bringing the majority of biosimilar medicines to Australia in the foreseeable future.[4] Medicines Australia has three key principles in relation to medicines, which includes biosimilars:

1. Decisions regarding all medicines should be based on appropriate and well understood standards of scientific and clinical evidence
2. Prescribing physicians (clinicians) should retain the right to choose what brand of medicine to prescribe for their patient, in consultation with their patient, and what is dispensed
3. Post marketing quality, safety and efficacy should be assured through robust pharmacovigilance and traceability mechanisms.

Clinical evidence regarding biosimilars means different things to different people, and Medicines Australia believes there is a need for strong alignment to ensure confidence in biosimilars amongst all stakeholders. Manufacturers have a responsibility to be transparent about the evidence in the development of biosimilars to give prescribers the confidence to have discussions with their patients about their appropriate use.

The PBAC decided last year that the determination of substitutability will be assessed on a case by case basis, and based on the available evidence, and that is what is currently happening. Whilst there are not multiple biosimilars on the market at this stage, there will come a time when this is the case and we, as stakeholders, need to understand the evidence for each biosimilar, how they reference to the original product and how they reference to each other, and if it is relevant to the way they are being, or will be, used in Australia.

Pharmacovigilance is obviously critical and includes not just knowing what brand was prescribed, but ensuring there is enough detail attached to the individual's record so the choice made by the prescriber, in conjunction with the patient, is respected when the medication is given. Where substitution has been established, consistent with the above mentioned principles, pharmacist notification of dispensing decisions to the prescribing clinician is important to enable effective pharmacovigilance and traceability.

It is necessary to be able to track and trace the individual medication (i.e. brand name and batch number) to ensure that if there are any issues, they can be followed up quickly and efficiently, in the best interests of the patient. Recording accurate details of the medicines prescribed to an individual would make this a lot easier.

4. https://medicinesaustralia.com.au/about-us/our-members/

WORKSHOP OUTCOMES

A series of workshops consolidated the insights and experiences of the participants representing a broad range of perspectives across various sectors of the healthcare community. Each workshop looked through the lens of the objectives of each National Medicines Policy pillar.

The Forum's workshops were framed around the four pillars of the National Medicines Policy including:

1. Timely access to the medicines that Australians need, at a cost individuals and the community can afford
2. Medicines meeting appropriate standards of quality, safety and efficacy
3. Quality use of medicines and,
4. Maintaining a responsible and viable medicines industry.

The series of workshops consolidated the insights and experience of the participants representing a broad range of perspectives across various sectors of the healthcare community. Looking through the lens of the objectives of each National Medicines Policy pillars, the overarching aims of the workshops were to:

- Explore the unique opportunities and challenges presented by biosimilars entering the market
- Identify what is established that is working well, what could be improved or modified, and what are the current gaps needed to be filled
- Discuss what stakeholders need to be involved in driving forward various initiatives, and in what capacity and,
- Commence introductory discussions on how these initiatives might be put into practice and the appropriate timings of these discussions.

Below are four summaries of the respective workshops and the full workshop outcomes have been provided as an appendix.

WORKSHOP 1: ACCESS TO MEDICINES

Ensuring access to biologic and biosimilar medicines for all Australians

Framed around the first pillar of the National Medicines Policy, this workshop focused on ensuring timely access to the medicines that Australians need, at a cost individuals and the community can afford.

The aim of the workshop was to identify the considerations unique to biologics and biosimilars that need to be addressed throughout the medicine journey to ensure timely access to these medicines in the future; to consider how these are currently being addressed and where the gaps are; and to agree on priorities to address these gaps.

Biologics are expensive medicines. Part of pillar one addresses affordability and the cost to the taxpayer, the cost of manufacturing, and the cost of storing in pharmacy. If wasted it is a significant loss to the healthcare system and influences how many of these medicines can be kept within pharmacy (potential leading to limitations around access).

In terms of what is already in place to ensure access, the general consensus was that much of the architecture that is needed already exists through TGA assessments and PBAC determination on access to funded therapies. When bearing in mind affordable access, a key consideration is that in Australia, until biologics and biosimilars are listed on the PBS, they are not readily accessible to the majority of people. International regulatory assessment methods, such as used by the EMA and FDA, could also be utilised.

There was concern around the restrictions on access to both biosimilars and biologics even after they are listed on the PBS. It was noted that for some conditions, these medicines are only accessible after other therapies have been tried and failed. In addition, there are only a limited number of opportunities a patient would have to access one of these medicines. For example in each of the inflammatory arthropathies, including rheumatoid and psoriatic arthritis, and ankylosing spondylitis, there is a limit to the number of biologics a patient can try. A patient will not have the opportunity to trial all available biologics and if therapy with the maximum number of biologics is exceeded and is unsuccessful the patient will have no further opportunities to apply, even when a new biologic becomes available.

There were discussions questioning whether such restrictions provide people enough opportunity to reap the benefits of such tailored medicines; and if in fact, they are counterproductive and misaligned to the core ethos of National Medicines Policy pillar one regarding improving access to medicines.

The naming of biosimilars and how this will be carried through on labelling and packaging in a way that people can understand what medicine they are getting and understand when their medication is changed, was seen as particularly important.

There is a clear need to increase confidence in biosimilars, particularly amongst prescribers, pharmacists and consumers, and how to achieve this was a major theme of discussion. The questions included, what data do we have, who has access to it, and how do we facilitate access to that data and collect the data we need? There is a lot of work to be done around most effectively collecting the data, getting it to the right people and using it in a way that improves confidence in what biologic medicines can do to improve the outcomes for the patient, and confidence in the use of biosimilar medicines, including if a patient is asked to consider switching.

A critical priority identified in this workshop was pharmacovigilance and how that links to data and the accurate and comprehensive collection of adverse events. This will require a robust monitoring system that shows if/when things go wrong, so that a response can be made, including the utilisation of eHealth records that are complete and support robust pharmacovigilance.

KEY PRIORITIES FOR FURTHER CONSIDERATION

- **Unlocking further opportunities for patient access:** Current PBS restrictions significantly limit the opportunities for consumers to access biologic medicines. PBS access should be consistent with the core ethos of National Medicines Policy pillar One.
- **Building a supply chain framework for the future that will ensure savings:** Biologics are expensive medicines and any decisions need to consider the cost to the taxpayer, the cost of manufacturing, the cost of storing in pharmacy, and if wasted, the significant cost to the healthcare system.
- **Certainty around naming:** The naming of biologic medicines was seen as particularly important, as how this is addressed will directly affect access to and confidence in biosimilars.
- **Clarity of data requirements and access to data:** Accessibility will rely on effectively collecting the best data on patient outcomes and providing it to the right people. Key questions include:
  - What data do we have?
  - Who has access to the data?
  - How do we facilitate access to the data?
  - What further data is needed?
  - How is this data most effectively collected?
- **Expanded pharmacovigilance:** The systematic collection of data i.e. electronic platform, to most effectively manage the issues associated with use of biologic medicines has the opportunity to instil greater confidence in the use of biosimilars.

WORKSHOP 2: QUALITY, SAFETY & EFFICACY

Understanding the regulations, standards and systems Australia will need to ensure the quality, safety and efficacy of biosimilar medicines in a rapidly changing environment

National Medicines Policy pillar Two is centred on ensuring the quality, safety and efficacy of medicines. This workshop explored matters including the collection of and access to data, systems, standards, processes, regulation and reporting. These matters were discussed in the context of initiation, substitution and multiple switching between biologics and biosimilars, and patient follow-up. Participants considered what Australia currently has in place, what works well, what needs improvement and what needs to be added.

It was agreed that there is much already in place and working well to support the quality, safety and efficacy of biologics and biosimilars, including:

- The TGA, in regulating the medicines that can be used in Australia
- The PBS/PBAC, in funding medicines, giving greater opportunity for access
- Medicines industry, through their manufacturing and adverse event reporting processes
- The digital capture of prescribing and dispensing data for individuals, both for PBS and private prescriptions
- Academia/universities, a large number of which are collecting comprehensive data and undertaking research.

Whilst there are a number of effective data collection processes in place, the systematic and comprehensive collection, consolidation, distribution of and access to patient-centred data was the key topic of discussion. The participants acknowledged there is currently a broad range of data available but there is significant potential to both add to and use this data more effectively.

When considering the gaps and what needs to be improved to ensure the quality, safety and efficacy of biologics and biosimilars, four key areas were identified:

1. **Evidence base** – Improved data on the impact of switching was seen to be key. This could be from additional randomised controlled trials, prospective naturalistic designed and retrospective studies, and/or recording and collating data via electronic health records. This data also has the potential to provide insights into why a patient may have failed on a biosimilar treatment so that improved targeting may also be an outcome. In addition, an improved understanding of the evidence of how biologics and biosimilars can be used in current practice is imperative to continue strengthening prescriber and patient use of biosimilar medicines.
2. **Systematic collection of data** – The collection of patient-centred data, from prescribing and dispensing to post-market findings, may facilitate a more integrated approach to patient care as healthcare professionals are able to track the patient along their treatment journey. This could generate a comprehensive, rich source of data that would ideally be accessed by all the healthcare team as well as the patient and their carer. This could facilitate shared learnings, identification of similar treatment paths and collaboration of findings. There would be benefits in exploring how this approach could be weaved into current clinical workflows and practice. The participants suggested biosimilars might offer an opportunity to tap into the engaged and motivated clinicians and patients, using the initiation of a biosimilar as a 'trigger' for the formation and use of an eHealth record that would support this collection and use of real-life data.
3. **Pharmacovigilance** – The workshop participants recognised that, although there are adverse event reporting systems available in Australia, their use is inconsistent and incomplete. There are important elements to ensuring quality and safe care for patients that are not included in current systems or processes. In addition, there is a lack of knowledge and understanding of the impact of the risk-management plans that are often part of current TGA and PBAC processes. A shared vision across the workshop was for a more comprehensive, connected and patient centred system that is harnessed more actively to inform and support the safety of clinical decisions. The ability to systematically capture and share the patient centred data, as described above, fundamentally raises the level of pharmacovigilance as it continues to build on and grow the evidence-base. This is likely to improve patient care, enhance post marketing surveillance, and inform the development and design of prospective studies i.e. Australian vs. international studies.

KEY PRIORITIES FOR FURTHER CONSIDERATION

- **Increasing the evidence base:** There is a need for both pre-market and prospective studies, in particular around switching / multiple switching, to ensure quality, safety and efficacy and strengthen prescriber / consumer confidence in biosimilar treatments.
- **Becoming more systematic and collaborative in data collection efforts:** There is the opportunity to identify a systematic, electronic process for capturing prescribing, dispensing and post market patient centred data. This could be achieved through leveraging the highly engaged healthcare professionals, patients and industry to collect and share data, develop more comprehensive findings to continue to improve and support decision making at all stages; registration, reimbursement, prescribing and dispensing.
- **Developing a collaborative and integrated approach to outlining acceptable quality, safety and efficacy of biologics and biosimilars:** In particular, clinicians and patients need to provide their views on 'acceptable' response and adverse events to a particular treatment. This then needs to flow on to a more comprehensive and collaborative pharmacovigilance system, including determining how aspects are measured.

WORKSHOP 3: QUALITY USE OF MEDICINES

Ensuring confidence in biosimilar medicines at every step of the patient journey

This session was designed as a natural progression from workshop two, and was built around the third National Medicines Policy pillar - supporting the quality use of medicines through education and information for all stakeholders along the continuum of care. The aim of the session was to identify the resources and support required beyond the Government's current education initiative, to ensure broad confidence in the judicious, appropriate, safe and effective use of innovator biologics and biosimilars, while ensuring that patient outcomes are optimised and the future potential of biologic therapy is fulfilled.

A key facilitator for the quality use of medicines is information. Stakeholders need to not only consider health literacy, which was also highlighted in workshop 2, but "medicines literacy". This is because all people involved in the patient journey need to appreciate what is unique about biologic and biosimilar medicines in order to be confident in any decision making regarding their use. This is likely to be challenging as evidenced by the introduction of generics; issues concerning their use are still not entirely understood by a significant proportion of consumers and healthcare professionals (HCPs).

Providing information, tools and resources that can support shared decision making are fundamental. Whilst there are some very good information sources currently available that have been developed by different stakeholders (e.g. Arthritis Australia), some resources aren't suitable for all purposes. Certain resources can be disjointed in the way information is presented and sometimes the information can be conflicting and potentially confusing for consumers - and even for healthcare providers who are trying to explain these concepts.

To provide up-to-date information supporting confidence in biosimilars, and enable shared decision making about their use, an initiative worth considering is the development of a comprehensive and universally used Q&A resource, detailing likely questions a consumer may ask. This has the potential to support consumers seeking information independently, as well as serve as a guide for clinician discussions with patients about these medicines.

High quality resources are important and could be developed in multiple formats given the variety of preferences individuals have when receiving information. Information provided should be:

- Be setting specific depending on the clinical group and how the medicine might be used. *Note: care should be made to provide consistent information across a range of settings where possible.*
- Be written from independent and trusted sources e.g. Australian Medicines Handbook or NPS MedicineWise). *Note: Other means of deriving and/or distributing information should be considered e.g. professional societies.*
- Provide and maintain up-to-date information

Content conveyed should include:

- Potential harms (safety)
- Likely benefits (effectiveness)
- Cost issues: Under the National Medicines Policy, quality use of medicines includes timely access to medicines at a cost that the individual and the community can afford, and appreciating this likely cost and impact is important.

Continuity of information that provides information about specific biologics used across healthcare settings is critical i.e. eHealth initiatives have the potential to enable the transfer of information and opportunity to identify potential gaps in information. In the interim, further guidance concerning the timely communication of information is important.

Confidence will be built if healthcare professionals believe the proposed benefits of using biosimilars including greater access to medicines for consumers, reduced costs, and return on investment to sustain and improve the healthcare system will be realised with no significant harm. The progress towards the achievement of these benefits should be widely communicated and publicised.

The strategies used to build an evidence base for safety and effectiveness should incorporate the ability to translate the evidence in a timely manner. Where there is a lack of evidence for a practice, it should be stated rather than ignored. When high quality information becomes available, resources should be available to ensure the information is incorporated into the designated resources in a timely manner.

KEY PRIORITIES FOR FURTHER CONSIDERATION

- **Centralising information that is easily accessible for all stakeholders:** Making information readily available, up-to-date and with a central point of contact will avoid mixed messages and confusion.
- **Ensuring comprehensive impartial information:** There are many stakeholders with differing needs and perspectives, so providing for all will be critical.
- **Evolving guidelines and data specifically around switching (and multiple switching as the market grows):** To get more meaningful data, a systematic approach will be needed.
- **Ensuring continuity of patient specific medicine information across and within healthcare settings:** Information shared (i.e. via an electronic platform) across healthcare disciplines is likely to support the team involved in an individual's medicine journey by providing consistent treatment recommendations.
- **Developing tailored and practical education resources to minimise mixed messages:** Providing information, tools and resources to support shared decision making i.e. universal Q&A for both clinicians and consumers has the potential to support consumers seeking information independently, as well as serve as a guide for clinicians' discussions with patients about these medicines.

WORKSHOP 4: RESPONSIBLE AND VIABLE MEDICINES INDUSTRY

The multi-stakeholder commitment to continued sustainability and innovation in the medicines industry

This workshop was framed around the fourth National Medicines Policy pillar - continuing to ensure a responsible and viable medicines industry in Australia. The aims of this session were to gather insights on what a responsible and viable industry means for each stakeholder in the context of emerging biologic and biosimilar medicines in Australia, identify any unique opportunities and challenges that may need to be addressed under this pillar to ensure the future success of biologics and biosimilars in Australia, and highlight the opportunities and challenges already being addressed as well as the gaps that should be considered.

The key points from this workshop are outlined below with a full discussion outline in Appendix 1.

What does a responsible and viable medicines industry look like?

- For patients, it was acknowledged a viable industry provides access to safe, high quality medicines. A responsible and viable industry allows for better access to these medicines in Australia, as well as research into future treatments and clinical trials.
- For clinicians, a responsible and viable medicines industry provides access to new products to prescribe to patients, provides access for their patients to clinical trials, supports investigator-led research opportunities, ability to contribute to advisory boards, and is a reliable source of product information and education.
- From the Government's perspective, the importance of a responsible and sustainable medicines industry is that it provides economic benefit through taxation, employment and export dollars, as well as access and supply, greater choice in treatments, better health outcomes and more clinical trials.
- For the industry, this means access to the market for medicines, reward for innovation, return on investment, investment in collaborations for research and long-term sustainable policies, and ability to invest in further research and clinical trials.

What factors are critical for the introduction of biologics and biosimilars?

- Patients want to know more about the risk assessment being made for them on these medicines. Currently, risk assessments on behalf of the patient are devolved to the Government, however, patients want to be more involved in the decision making process.
- A key question from clinicians is whether the introduction of new biosimilars will expand access so that they can treat more patients than they are able to within the current restrictions.
- The Government is looking at how to use the introduction of biosimilars to reduce expenditure on the PBS, create cost efficiencies and increase medicine access and supply.
- While, for the industry, long-term investment and research on unmet clinical need is imperative, in addition to stable and predictable policies.

To help support the introduction and uptake, incentives are critical for industry to research and develop new biologics (which will lead to new biosimilars down the pipeline); for clinicians to choose and prescribe biosimilars to their patients; for patients to take biosimilars; and for pharmacies to dispense biosimilars. While some incentives are already in place, further clarity on the incentives for biosimilar uptake and education were identified as critical to establishing and maintaining confidence in their use. The Government's current incentives for innovation, the biosimilar education and awareness initiative, and a focus on research and development of NHMRC and universities, were noted as a positive step.

Having clarity about the incentives for various stakeholders will be important. Currently, patients have incentives to use biosimilars, but there are ways to improve these, by expanding access to a particular group of patients as costs decrease or allowing patients to be more involved in the risk assessment decision so they can make more informed decisions.

While clinicians acknowledged cost savings can be achieved through the introduction of biosimilars, such cost considerations are not necessarily front of mind for clinicians when considering what to prescribe their patients and discussing this with them.

It was acknowledged there are some market measures that have been introduced which will incentivise the development and marketing of biosimilars by the industry e.g. recent clarity on decisions in favour of substitution, where supported by appropriate evidence was recognised as an incentive. However, clinician and patient confidence in such mechanisms is also critical to ensure successful market uptake, and if this is not successful there may need to be other measures put in place.

It was acknowledged for pharmacy, substitution can be seen as an incentive but whether that is going to be realised in practice is dependent on other measures at play including the patient's, clinician's and the industry's choice to support such measures.

What is currently in place to ensure a responsible and viable medicines industry?

The $20million *Biosimilars Awareness Initiative* was acknowledged as an integral and positive initiative to continue to improve understanding of biosimilars.

It was acknowledged that biosimilars will create savings for the Government (through a legislated reduction in price of 16 per cent when the first biosimilar enters and more over time through price disclosure). Such savings can be invested in new medicines. Currently, as these price reductions occur access restrictions are unchanged, and in this context it was acknowledged the introduction of biosimilars may present the opportunity to re-trigger a consideration of access arrangements for the relevant biologic/biosimilar.

Clarity around managing off-label use in the area of biologics and biosimilars was another critical factor identified. It was acknowledged industry does not communicate or promote, nor does the Government fund, off-label use. As data to support new indications or expanded use becomes more available there are some opportunities to consider how to utilise cost savings to fund these.

The TGA reviews all medicines that are submitted for registration, and the PBAC reviews all medicines that are submitted for inclusion on the PBS. It was acknowledged this established process will naturally continue to evolve to meet the challenges and opportunities ahead, and collaboration from all stakeholders will be advantageous.

KEY PRIORITIES FOR FURTHER CONSIDERATION

It was acknowledged there was a lot of commonality in views across stakeholders

- **Industry will be central in addressing future unmet medical needs, by bringing new treatments to market:** In this context, savings from biosimilars are able to be invested in new medicines or in expanding access.
- **Clarity and education on the incentives for biosimilar uptake (for clinicians, pharmacy, patients and the medicines industry) is important:** Each stakeholder has a role to play in ensuring these incentives are understood, and in building confidence.
- **Keeping the patient at the centre of the decision making process, by improving health literacy and via shared decisions making processes:** To enable a patient's greater understanding of their treatment pathway.
- **Encouraging continued research and commercialisation of new medicines:** through collaboration with industry and academia.

The organising committee would like to thank all the delegates and organisations who attended *The Biologic and Biosimilars 2020 Forum*. Your contributions and insights on the day have been invaluable in shaping this report.

The Biologic and Biosimilars 2020 Forum was funded by Medicines Australia.

APPENDIX: WORKSHOP NOTES

This appendix is a direct representation of the workshop notes and discussions captured on the day of the Forum.

These notes are included here as an extended point of reference for this report. They provide further insights from the participants in alignment with the workshop summaries detailed throughout this report.

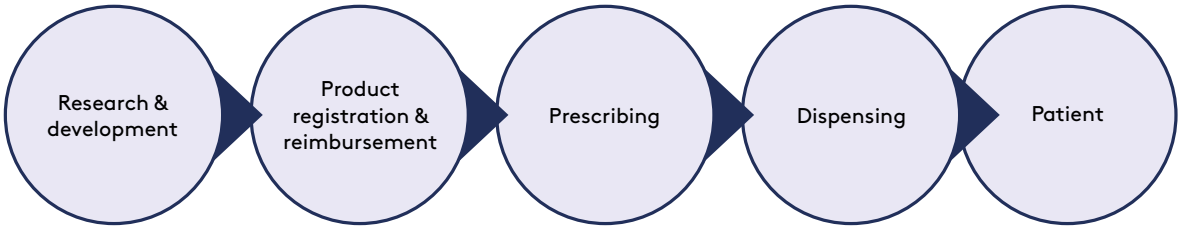
WORKSHOP 1: ACCESS TO MEDICINES

Ensuring access to biologic and biosimilar medicines for all Australians

This section is a direct representation of the workshop 1 notes and discussions captured on the day of the Forum.

Workshop structure

For this workshop participants were divided across five stations, each representing the stages in the medicine journey (see below). Each group was asked to consider key questions through the lens of each stage of the medicines journey i.e. unique supply chain considerations, what is already in place and where are the gaps.



Objectives

The objectives of Workshop 1 were to identify:

- The considerations unique to biologics and biosimilars that need to be addressed to ensure timely access to these medicines in the future.
- How these considerations are being addressed, the gaps and what additional factors could be critical for this future success.

Key questions

The group was then asked to workshop the following questions:

- What are the unique supply chain considerations for each stage of the medicine journey?
- What's already in place?
- What are the gaps?
- What are the top priorities that need to be addressed?

OUTCOMES

Q1: What are the unique supply chain considerations for each stage of the medicine journey?

Product registration and reimbursement	• Naming - how will it work? • PBS major submission / different to generics • How much data is given to Economics Sub Committee (ESC)? • Phase III clinical trials • Head to head clinical trials • 'a' flagging • Case by case PBAC assessment • Criteria for registration / reimbursement • Where does the TGA sit? • Follow European advice? • It costs more to produce a biosimilar medicine compared to a generic medicine which may mean there are less biosimilars on the market • Sustainability of PBS
Prescribing	• Restrictions – PBS criteria, formulary access, protocols • Off-label use, compassionate access, medicines access programs • Mechanics of prescribing – Use of software, assistance / complexity, hospital software limitations, substitutions • Setting – Where a product needs to be administered
Dispensing	• Access – PBS criteria, off label use, compassionate access, medicines access programs • Affordability – Cost of drug • Manufacturer not supplying at PBS cost • Cost of holding multiple forms of high cost drugs • Delay in supply chain (geographical) • Cold chain issues • Hospital governance over what biologics are on formulary and other biosimilars
Patient	• Overall cost and benefit to the community needs to be considered rather than just the medicine – E.g. Patients returning to work pay taxes and give back to the community • Need to be clear on product name (brand) and active ingredient – E.g. in hospital patients don't usually get the box, but they know the brand so they may receive a biosimilar but won't know • Health literacy – E.g. Patient understanding of medicines and medicine management, and the nuances of biosimilars

Q2: What is currently in place to address these considerations and where are the gaps?

	In place	Gaps
Product registration and reimbursement	• Regulatory framework • Reimbursement framework • Price disclosure • Available in other markets • Products on the market • $20 million for awareness • Proposed WHO guidelines for naming	• TGA – what role should they play? • Mechanisms to support uptake – what are they? • Move biosimilars to earlier in treatment (expanded access) • Switching guidelines • Pharmacovigilance not coordinated comprehensive e.g. medicines access programs • Clarity of data needed for PBAC • Extrapolation of indications • Multiple switching • Equitable system for all biologic medicines • Cost offsets • Where do the savings go? • Managing expectations of government / industry
Prescribing	**Restrictions - PBS criteria, Formulaic access, protocol (supply and in place)**	• Communication - between prescriber and dispenser • Variations in governance of medicines between hospitals • Data – Paediatric, positioning • Knowledge / awareness gaps • What needs to happen? • Data – gather information to cover gaps, data registry, dispensing data • Outcome data – we need efficacy, safety • Aggregating information that exists now – universal source of information • Personal electronic health record – analytics / reporting data

	In place	Gaps
Dispensing	• Wholesalers for CSO • Not urgent generally – ordering on demand • Hospitals – state contract brands • Hospital QUM principle of drug in group to lower the risk of the wrong product • Sterile compounding facilities	• Recording of batch numbers – using drug efficiently • Refrigeration space • Pharmacy not keeping all brands – do not substitute • Management of cost – (stock on hand) • Education around biologics – Community and hospital pharmacy – Patients • Guidelines for clinicians around biosimilars • Payment of wholesaler / drug co. – High cost different terms • Gaps between marketing to PBS listing – Compassionate programs
Patient	• Strict eligibility criteria • Not transparent to patients • Needs to be loosened to enable use of the new medicines • Introduction of the new biosimilars should open limitations • Strike out rule • Need to expand available information to educate patients on biologics / biosimilars as it applies to their diseases • Increase funding and use of speciality nurses as a source of support and education for patients	• Consistency of Care – Keeping the one pharmacist • Consumer oriented material • Multicultural / multi-language educational resources • Peer support groups can be a source • Leveraging the pharmacist in patient care and others involved in medical care = team approach e.g. infusion nurse, GP, Physio • Improving patient confidence

Q3: Amongst these gaps what are the top priorities that need to be addressed?

Priority 1

- **Expand access / reduce restrictions to biologics and biosimilars**
  - Keep level playing field for biologics and biosimilars
  - Restrictions such as number of times in a lifetime a person can try a biologic or biosimilar and the allowed number of switches need to be reconsidered / re-examined

Priority 2

- **Improve active pharmacovigilance**
  - This is essential to improve confidence and uptake of biologics and biosimilars
  - Product naming should be such so that consumers know the product and active ingredient of their medicines, including biologics

Priority 3

- **eHealth**
  - Australia needs a platform to share information with all stakeholders and this will contribute to pharmacovigilance
  - Data should be collected, shared and evaluated and use appropriate naming conventions

WORKSHOP 2: QUALITY, SAFETY AND EFFICACY

Understanding the regulations, standards and systems Australia will need to ensure the quality, safety and efficacy of biosimilar medicines in a rapidly changing environment

This section is a direct representation of the workshop 2 notes and discussions captured on the day of the Forum.

Workshop structure

Workshop participants were divided into five groups and through the lens of National Medicines Policy pillar Two, discussed the following:

- What systems / processes are already in place?
- What is currently working well?
- Where are the gaps / areas for improvement?

The group then considered these questions from the perspective of each relevant stakeholder (i.e. prescribers, dispensers, consumers, regulatory / reimbursement). Five key themes were identified and agreed by consensus. Following this, participants were divided again with each new group looking at each of the five identified themes and responding to a series of key questions (see below).

Objectives

The objectives of this workshop were to discuss what is needed – in terms of data, systems, standards, regulation, reporting etc. – to ensure the safety and efficacy of biologic and biosimilar medicines, especially in the context of substitution and multiple-switching.

Key questions

Taking into consideration the current regulations framework, levels of clinical data, evidence post registration and reimbursement, post-marketing surveillance undertaken, and systems for adverse event reporting, the participants were asked to workshop the following questions:

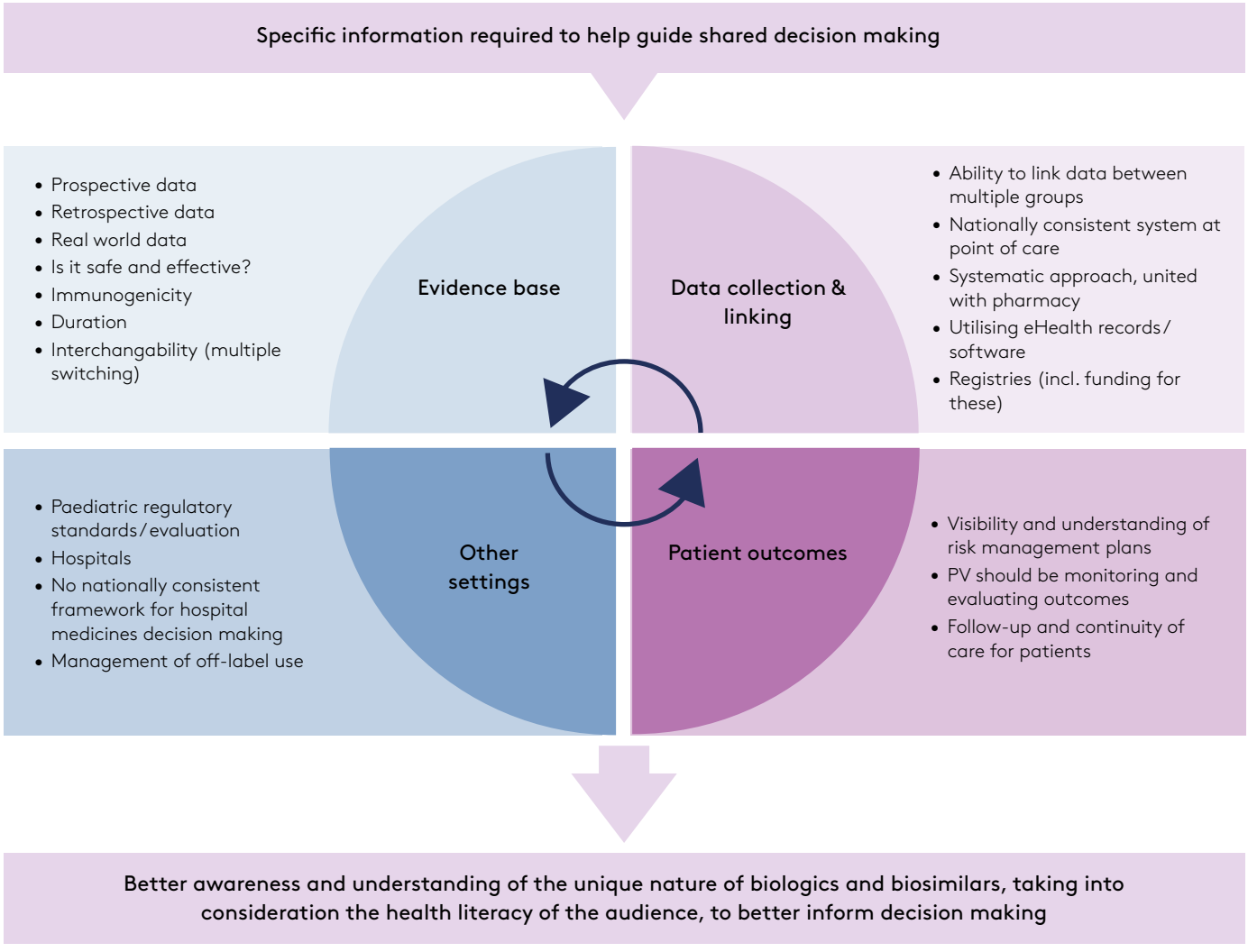
- What is already in place and currently working well to ensure the quality, safety and efficacy of biologics and biosimilars?
- What are the gaps? What needs to be improved?
- Do you have any ideas on how this priority could be progressed?
- What could be an effective first step?
- Who are the key stakeholders that would need to be involved?

OUTCOMES

Q1: What is currently in place and working well?

- The regulatory process to evaluate the safety, efficacy and quality of biosimilars including:
  - TGA guidelines
  - TGA evaluation / transparency (AusPar)
  - Risk based evaluation
  - Three levels of TGA evaluation
    - Licencing manufacture
    - Pre-marketing evaluation
    - Post-marketing surveillance
- Our pharmacovigilance system with risk management and requirements, and spontaneous AE reporting
- The Pharmaceutical Benefits Scheme – having universal national medicines funding.
- Medicines industry-funded clinical trials with long term follow-up.
- Managed access schemes where funding access is provided and the medicines industry monitors and reports back to keep PBS.
- IMS data collation of private and PBS scripts which covers 60% of pharmacies.
- Local registries such as those created by the ARA, GESA and international registries where Australian data is fed in.

Q2: What are the gaps and what can be improved?



Q3: What are the priorities, how could they be addressed and what stakeholders would need to be involved?

The following considers the first steps to address the prioritised areas for improvement.

Priority 1 – Evidence base needed to guide shared decision-making

First steps	Stakeholders
1. Randomised controlled trials (pre-market authorisation) covering: • Interchangeability • How many switches • Immunogenicity	Industry, clinicians, researchers
2. Naturalistic design studies • To provide a guide for use in practice • Case definition – clinical, interventional	Clinicians, researchers, professional bodies
3. Retrospective • Analysis of PBS use, dispensing frequency and switching (AE incidence) • Laboratory to explore case definition • Database of Adverse Event Notifications – clarify clinical options	Government, pharmacy, clinicians

Priority 2 – Improved data collection and linking

First steps	Stakeholders
Routinely collected data – "big data" including: • Individual patient level data • Better collated /organised at national level • Used to inform future clinical decisions	Government, clinicians, professional bodies
Improving approach to detection, recording and analysis of suspected adverse drug reactions from the front line	Government, clinicians, professional bodies
Medicine-focused outcome data (rather than disease-focused) • Links to PBS funding (initial and ongoing) • Potential for eHealth record to address, if well designed	Government, clinicians, professional bodies

Priority 3 – Improved patient outcomes

First steps	Stakeholders
Determine what is a valuable response and what is an unacceptable adverse drug reaction	Government, universities, clinicians, community incl. patients, pharmaceutical companies with an interest
Early conditional registration / reimbursement based on QSE	Government, clinicians, community incl. patients, pharmaceutical companies
Post-marketing, statistically reliable monitoring of efficacy and safety	Pharmaceutical companies, government

Priority 4 – Improved health literacy

First steps	Stakeholders
Consumer centered information about biosimilars • Tailored to the information needs of the individual, their condition, the delivery route and mechanism of action	Patient groups, professional bodies
Empower clinicians to confidently have discussions with their patients about biosimilars • Creation of a reliable source of information online • Develop discussion tools to support the conversation (e.g. pack of cards with key issues – what's of concern to me)	Professional bodies, clinicians, patient organisations and government

* NB: Given the unique requirements necessary to address the current gaps and improvements required for the use of biologics and biosimilars in other settings / patient populations and in light of time restrictions for the workshop, this aspect was not addressed by the group.

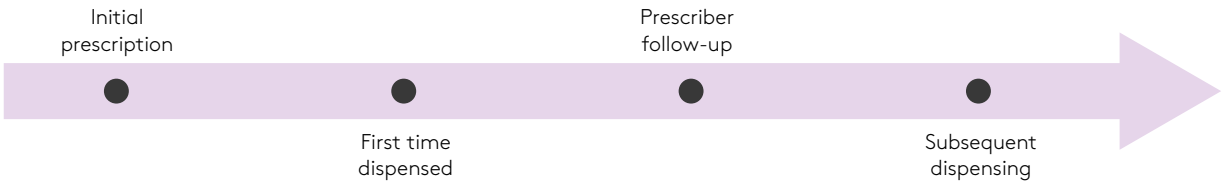
WORKSHOP 3: QUALITY USE OF MEDICINES

Ensuring confidence in biosimilar medicines at every step of the patient journey

This section is a direct representation of the workshop 3 notes and discussions captured on the day of the Forum.

Workshop structure

Participants were divided into groups and each group asked to discuss what considerations need to be addressed throughout the continuum of care:



From these discussions, the top five themes were identified, and participants were asked to consider what support / resources would be needed to have confidence in the decision making for each of these themes. In addition, participants were asked to consider what support / resources already exist and where there are still gaps.

Objectives

The objectives of Workshop 3 were to identify the resources and support required along the continuum of care to ensure broad confidence in the judicious, appropriate, safe and effective use of innovator biologics and biosimilars while ensuring that patient outcomes are optimised and the future potential of biologic therapy is fulfilled. The scenario presented was of a biological treatment-naïve patient with a condition for which a registered innovator biologic and biosimilar are available on the PBS.

Key questions

The group was then asked to workshop the following questions within the context of the established systems and processes:

1. When it comes to biologics and biosimilars what needs to be considered at each point on the continuum of care?
2. What information / support is needed to have confidence in assessing these considerations?
3. What is already being addressed to support these areas?
4. What questions remain unanswered / where are the gaps?

OUTCOMES

Q1: When it comes to biologics and biosimilars what needs to be considered at each point on the continuum of care?

Initial prescription	First time dispensed
Patient suitability / clinical criteria • Diagnosis • Previous experience • Prior therapies • Choice of biological medicine • Compliant with registered indication / PBS prescribing criteria • Biosimilar or originator • Availability of medication • Patient lifestyle / location • Age / care • Accessibility of administration mode • Any markers for effectiveness • Any relevant data / info to make the most appropriate choice of treatment **Prescriber approach with patient** • Physician needs to show confidence with patient and the patient needs to trust their doctor – but it needs to be a shared decision making process – What are the patient's preferences? – Patient provided educational materials about the treatment they are being prescribed – Encourage patient to discuss / raise any concerns they have at any time, not just wait till next appointment • Ensure patient understands the name and dose of their medicine and other relevant issues • Tick / do not tick the substitution box	• Where is the script? • Procurement, how long will it take to obtain? • Discussion between patient and pharmacist regarding brand selection • Patient education including provision of CMI • Consumables or supportive care • Storage conditions • Enroll in patient support program • Plan for subsequent doses • Plan for when next PBS forms due • Pharmacist / doctor / nurse to assess patient knowledge and any gaps • Verify prescriber intent – 'no substitution box' • Notify the patient if they are getting prescribed the biosimilar and check if the patient is ok with it • Reinforce and supplement (if necessary) prescriber information

Follow-up appointment	Subsequent dispensing

• Check clinical response
• Possible adverse drug reactions?
  – Report any adverse effects
• Blood tests as necessary
• Check adherence / any issues?
• Is there any new information available pertaining to efficacy, safety?
• Reinforce original information
• Does patient have any questions?
• Options available if needed
• Time to peak response?
• Ask the patient if they are comfortable with delivery mode of treatment
• Consider if there are changes that will need to occur to any other elements of the treatment
• Provide patient educational information on switching considerations if necessary
	• Which brand?
	• If box is not ticked will I substitute?
	• Medication AE / treatment efficacy monitoring
	• Adherence
	• Further education
	• Patient experience with treatment
	• Has patient been on any new meds that could now interact with original biologic / biosimilar?
	• Re-check patient knowledge
	• Ask patient if they have had any issues / reactions
	  – Report any adverse effects
	• What to do if product no longer stocked
	• How to encourage patient to attend the same dispensing pharmacist
	• Reinforce and supplement (if necessary)

Q2: What are the key themes regarding biosimilar choice?

HCP-focussed

1. Supporting the acquisition of knowledge to make informed decisions and encourage shared decision making
2. What data is required to inform switching?
3. Choosing between an innovator biologic and a biosimilar for the initial prescription

Consumer-focussed

1. Instilling patient confidence and understanding about biosimilars including:
   - Shared decision making
   - Understanding potential harm and likely benefits
   - Understanding treatment goals
   - Understanding the long journey
   - 'a' flagging and importance of understanding issues around branding

Q3: What information / support is needed to have confidence in assessing these considerations, what is already being addressed and where are the gaps?

Consumer focused

Instilling patient confidence and understanding about biosimilars

What information / support is needed	• e-health records • Good information for clinicians and patients that is: – Age appropriate – Sensible – Considers the health literacy of the individual – Easily accessible – Process for reiteration of information with patient – Clear, concise and appropriately targeted at the intended audience – Sources of information
What already exists?	• Scheduling / compliance aids • Confidence in medical profession • Multiple sources of information about the drugs • Capacity to provide the patient with a care plan • Patient support organisations
Where are the gaps?	• Consistent national information for clinicians, patients and pharmacists • Lack of take up of PSO's / consumer groups / more coordination with patient groups

Health professional focused

Supporting the acquisition of knowledge to make informed decisions and encourage shared decision making

What information / support is needed	• Appropriate education resources for: – Patient – HCPs (prescribers, pharmacists, nurses) – Pharmacists • May be molecule-specific rather than disease specific (particularly relevant for safety information) • Needs to clarify the difference between biosimilars and generics • Who should provide the education to the consumer? – Could be a Nurse, Prescriber or Pharmacist • Who could facilitate education uptake? – Could be consumer organisations, sponsors, Department of Health and / or professional societies • Information for HCPs should be consistent
What already exists?	• Australian Rheumatology Association Disease and Medical Information[5]*
Where are the gaps?	• Physician needs access to latest research • Electronic health record • Hand-outs / materials given to patient about their treatment, places to go to get support, further information about their condition

What data is required to inform switching?

What information / support is needed	• Details on previous use and whether switching has occurred previously • Data on multiple switching – is it an issue? • Data on one-way switching • Data on staying with the same product – biologic, biosimilar • Real world data on switching – prescriber, pharmacy • Inadvertent v deliberate
What already exists?	• CATAG Guiding principles (currently under revision)* • Current international studies*
Where are the gaps?	• Clinician acceptable outcome data – numbers vs quality of life • Patient understanding about switching • Understanding patient outcomes from switching – How easy it is to measure outcomes – What is the disease variability – What patient characteristics can be quantified • Methods to assess whether switching has happened

5. For further information http://rheumatology.org.au/community/PatientMedicineInformation.asp

*Post-meeting note

Choosing between an innovator biologic and a biosimilar for the initial prescription

What information / support is needed	• Education / information for the doctor, patient and pharmacist • Demonstration of access to the medication (to see the "greater good") • Audit – time poor clinicians, part of routine practice • Marker for effectiveness and safety (outline immunogenicity)
What already exists?	• Consumer medicines information and product information • Reference texts: AMH • Industry produced information (although query whether this is positively or negatively received) • PBAC decision making documents • NPS Radar (NPS MedicineWise) • Patient groups and professional body produced information
Where are the gaps?	• Information from an impartial source • More simplified information

WORKSHOP 4: RESPONSIBLE AND VIABLE MEDICINES INDUSTRY

The multi-stakeholder commitment to continued sustainability and innovation in the medicines industry

This section is a direct representation of the workshop 4 notes and discussions captured on the day of the Forum.

Workshop structure

Workshop participants were divided into four groups, with each group being asked to consider two key questions through the lens of the patient, the clinician, the government and the medicines industry:

1. What does a "successful and viable industry" mean for each stakeholder group?
2. What factors will be most important to the introduction of biologics and biosimilars for each stakeholder group?

From these discussions the top four factors were identified. Participants were then asked to consider what is already in place to address the issue/factor and what still needs to be done.

Objectives

A responsible and viable medicines industry is an important part in bringing medicines to patients and in assisting quality use of medicines, by supporting research and development, continuing professional education, ethical promotion, and the availability of appropriate information about medicines for consumers and health practitioners. In this context, the key objectives of this session were to:

- Gather insights on what a responsible and viable industry means for the successful introduction of biosimilars in Australia
- Identify the unique areas that need to be addressed under this pillar to ensure this future success
- Highlight the areas that are already being addressed as well as the gaps to be considered

Key questions

The group was asked to workshop the following questions.

1. What does the concept of a "successful and viable industry" mean for this group?
2. Which of these factors will be most important in terms of the introduction of biologics and biosimilars?
3. What is currently being done to address this issue/factor?
4. What still needs to be done?

OUTCOMES

Q1: What does the concept of a "responsible and viable medicines industry" mean for each of the key stakeholders?

Government

- Economic benefit via tax, employment, costs, manufacturing and export
- Dependable access for Australian patients to medications and a reliable supply
  - Choice for payment, introduction of new meds
  - Healthy patients means increased productivity
- Early access for patients & HCPS, local experience
- Investment in science/basic research
- Healthy industry provides the ability for many companies to compete
  - More competition means drugs at lower prices
  - Cost Effective

Medicines Industry

- Willingness to invest in long term drug development
- If it is viable, presence of products/manufacturers in the market
- Willingness to invest in research and development or clinical trials in Australia
  - collaboration between industry and academia
  - jobs for highly educated people
- Making the most of Australian science
- Options for patients and prescribers for both biosimilar and originator therapy
- Addressing future unmet medical needs
- Ability to contribute to improving health policy

Clinician

Access

- To new medicines and research
- No change restricted criteria
- Lower cost to gov. higher access
- Post market review could consider broadening access
- Patient group advocacy
- Link introduction of biosimilar & improvement of access

Cost

- Listing of Biosimilars and cost for government
- Incentives to drive uptake

Patient

- Access to safe, high quality medicines
- Good outcomes for patients
- Innovation – new medicines, research
- Education for doctors and patients
- To encourage proper dialogue about treatment and how patients can be more involved in research, design, decision making
- Access to medicines, clinical trials
- Best practice
- Issues
  - Patients disconnected from industry, regulatory barriers
  - Viable industry "not just pharma"

Incl. researchers, pharmacy, distribution, supply chain etc.

Q2: Which factors will be most important in terms of the introduction of biologics and biosimilars?

Government Access and supply of effective and safe biologic and biosimilar medicines in a cost efficient manner	**Industry** Long-term investment in research of new biologics, focusing on areas of unmet clinical need, to provide pipeline for new biosimilars and clear guidance for introduction and uptake of new biosimilars
Clinicians Will the introduction of new biosimilars expand access to treatments for more patients	**Patients** Enabling patients to make decisions / information / education
Overarching Creating incentives to drive uptake of biosimilars: • Industry to develop • Clinicians to prescribe • Patients to take • Pharmacy to dispense • Core tenants are: access, cost, education, shared responsibility, consistency, reliability	

Q3: What is and isn't being done to address these factors?

	Being done	Still needs to be done
Access and cost	**Cost:** • Biosimilar cost down (16% and more) through price disclosure expected **Access:** • Restrictions – can they change, could more be done?	• Use post market review mechanisms to secure expanded access • Patient / GP advocacy
Choice and education	• TGA reviews all medicines and PBAC reviews applications • Incremental innovation is occurring • Reliable, regulation • $20m biosimilar awareness initiative	• Implementation of the $20m biosimilar awareness initiative – transparency of its direction and scope • Continue commitment to choice • Improve health literacy
Innovation	• Government incentives for innovation – Research and development focus of NHMRC / Universities • "Auditing" quality of care • Biosimilar awareness initiative	• Commercialisation of innovation • Implementing change from audit on quality of care outcomes • Not consistent across disease areas – More sharing of information on what is being done – How to effectively engage with consumers

Incentives	• Clinicians, tax payer saving • Industry, market forces, i.e. "a" flagging • Pharmacy, "a" flagging	• Maximise savings and maximise access (TGA / PBS gaps)
Risk tolerance	• Medicines information – Platforms – Pharmacy – Doctors – PBS, TBA, PBAC	• Less duplication of research and development • Less Red Tape • Shared decision making • Health literacy – before you get sick • Government determines risk tolerance – This means patients only get options once quality and safety is known • Off label use is a dirty word – Industry can't interact – Government doesn't fund research in this area • Rare diseases • Pediatrics
Other considerations	• Incentives – not clear for some stakeholders • Reliability – longer term data / unknowns • Patient incentive is quality of life, with contribution back to society, functioning member of community – Access / incentive – Education – Risk tolerance • People already on treatment vs. people not yet on treatment • Not "one nail and one hammer"	