

Introduction

FOSTERING THE ESSENTIAL VALUE OF BIOSIMILAR MEDICINES BY INSPIRING BEST PRACTICES

Report summarising multi-stakeholder perspectives,
June 2019

The following is a summary of discussions that took place between key stakeholders during the Medicines for Europe – International Generic and Biosimilar medicines Association Annual Conference in June 2019.

Session participants

Chair:

Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz

Panellists:

Gustaf Befrits, Health economist, Stockholm County Council, Sweden

Dr Paul Cornes, Oncologist, Comparative Outcomes Group, UK

Prof. Robert Duncombe, Director of Pharmacy at The Christie NHS Foundation Trust, Manchester, UK

Zorana Maravic, Director of Operations, Digestive Cancer Europe

Marnie Peterson, Chief Executive Officer, Generic and Biosimilar Medicines Association, Australia

Key discussion points

This panel aimed to explore and expose best practices from different geographies and stakeholders that ultimately contributed to improving patient's access to biologic medicines via better, faster, more efficient or more informed utilisation of biosimilar medicines.

Main success factors identified in the session were:

- Value to all the stakeholders needs to be tangible, create incentives such as benefit sharing.
- Continuous education of all the stakeholders needs to take place.
- Multidisciplinary approach in biosimilar adoption, involving physicians, pharmacists, nurses and patients in the process, but at the same time have a person, group or body who is a decision maker.
- Involvement of patients in open communication. As the patient is the end beneficiary it is important to put them in the centre of the discussion.
- All stakeholders are accountable, we have to align on the incentives and infrastructure.

Biosimilar medicines bring greater access to treatment: we want more patients to be treated and that is what binds us all.

Key outcomes

Setting the scene

The presence of generic medicines on the pharmaceutical market is essential to maintain the sustainability and credibility of the industry but also the sustainability and affordability of the health care system. For the same reasons, it is impossible to imagine the world without biosimilar medicines.

The value of biosimilar medicines for patients and healthcare systems is well recognized. There are many data on the safety and efficacy of biosimilar medicines; around the world multiple biosimilar medicines have been approved. Availability of biosimilar medicines improves access to treatment, ensuring patient access to key therapies. In the five largest European markets alone, biosimilar medicines have saved 14 billion EUR, allowing for reinvestment in healthcare systems.

The opportunities from biosimilar medicines have not been fully realised yet. The optimization of opportunities from biosimilar medicines differs a lot geographically, and even in the same country between different molecules and therapeutic areas. There is still an opportunity for healthier competition in the marketplace and for long-term sustainability. There is also a need for all stakeholders to be empowered to engage in embracing the opportunity biosimilar medicines bring and to identify misleading information about biosimilar medicines where it appears.

All stakeholders can benefit from well-functioning health care systems with biosimilar medicines onboard: patients, healthcare professionals, payers and manufacturers. At the same time, all stakeholders share the accountability in this system to define a sustainability framework for biosimilar medicines.

In the panel discussion different perspectives were presented from different parts of the stakeholder spectrum: patients, health care professionals, payers and the industry.

Strategic efforts to promote clinical use of biosimilar medicines

Marnie Peterson: Education and peer-to-peer communication

Australia has 10 years of exposure to biosimilar medicines with 21 products approved and 8 biosimilar medicines listed on the Pharmaceutical Benefits Scheme (PBS). Biological medicines accounted for 30% of PBS expenditure in 2017/2018 and 7 of the 10 highest cost medicines subsidised by the PBS were biologics.

In Australia, there are policies in place that support biosimilar uptake and make it easier for prescribers to prescribe biosimilar medicines (this includes uptake drivers such as: recommendations regarding treating naive patients and streamlined authority, in addition to “a” flagging, which supports pharmacy-level substitution). Despite this, the uptake of biosimilar medicines in Australia sits lower than in many comparable overseas markets.

Marnie Peterson presented the Educational Grant that GBMA (Generic and Biosimilar Medicines Association) received from the Australian government. The purpose of the grant was to support an appropriate uptake of biosimilar medicines through peer-to-peer education and health communication initiatives. GBMA Education (established by GBMA to administer the Grant) provides a platform for discussion and dialogue as well as to facilitate information exchange between healthcare professionals who can share their experiences with biosimilar medicines and originator biologics.

The project started in April 2018. GBMA Education collaborated with healthcare professionals (pharmacists and prescribers), manufacturers, industry bodies and government to shape the program. GBMA Education believed that the program would have good foundations to prepare all activities and materials only if all engaged stakeholders (including HCPs, manufacturers – originators & biosimilar medicines, and government), agree with key facts around biosimilar medicines. The Core claims were established, which are fully referenced statement of facts that provide unbiased information about biosimilar medicines. Those claims were purely educational, not promotional, not product specific and were related to biosimilar equivalence, cost savings and biosimilar use in clinical practice.

As a part of the program, GBMA Education organised its first Biosimilar Week 2019 held on 29 April – 3 May. This activity concentrated on the discussion around biosimilar medicines in Australia. GBMA facilitated health care professionals sharing their experience with biosimilar medicines. Videos were recorded and shared with all those who wanted to participate.

In the recorded interviews, the opinion leaders emphasised that:

- There is no difference in immunogenicity between reference and biosimilar products.
- The biosimilar medicines are safe, are efficacious, and there is no increased risk in immunogenicity.
- Despite initial concerns around safety and efficacy of biosimilar medicines in comparison to reference products, now with increasing experience with these products we see growing confidence in biosimilar medicines.
- The rigorous registration process of biosimilar medicines requires the manufacturer to provide high quality products with clinical evidence of safety and efficacy. TGA would not register a medicine if they were not very confident that it is entirely safe and effective.
- Some Australian healthcare professionals already have 10 years of experience with biosimilar medicines.
- There is no difference between reference and biosimilar medicines regarding efficacy and safety.
- From real world data and clinical evidence, we can be confident that biosimilar medicines are beneficial and certainly have a role in different therapeutic areas including rheumatology.
- Physicians have to provide information to patients about biosimilar medicines, to reassure them that biosimilar medicines are substitutable and equivalent, and that there will be no change in their disease control and in their adverse event profile.
- If both patient and physician are confident that the patient is receiving optimal treatment, then the response to treatment is likely to be maximal.

The next part of the programme will focus on the patients. Activities will include communications via patients' groups and social media channels and point-of-dispense support. There are also plans for: A Multidisciplinary Industry Workshop (4 Sep 2019) and a Biosimilar (Awareness) Week (April-May 2020). The main topics for these events are:

- Track and traceability and pharmacovigilance
- Patient-centric care
- Demonstration that the savings coming from the use of biosimilar medicines will be reinvested in the healthcare system that could potentially expand access to treatment and to introduce new therapies.

Dr Paul Cornes commented that 5 million Australian dollars sounds like a lot of money to invest in education, however if we put it in perspective it is only 0,5% of the spending on adalimumab in Australia to run this whole programme - equivalent to the cost of 31 patients on originator adalimumab for a year at US prices.

Gustaf Befrits: Payer perspective - Swedish example

Gustaf Befrits presented a Swedish example of the successful introduction of a biosimilar product (trastuzumab) in the oncology area in 2018.

As a first, the biosimilar infliximab was introduced in Sweden in 2014, one year after other neighbouring countries, for example Norway, where they performed a NOR-switch study to assess the impact of switching.

Switching is necessary to achieve competition dynamics during the introduction of biosimilar medicines.

In 2014 with the introduction of two biosimilar medicines: infliximab and etanercept, the Swedish payer commenced active strategic efforts to promote uptake of biosimilar medicines and achieve savings. On the supply side, there were tenders and confidential discount agreements. On the demand side they introduced benefit-sharing. Hospital administrations and clinicians who decided to switch patients to a cost-effective biosimilar medicine, got to keep the difference and to decide how to spend it best.

The key element was the Swedish experts' confidence in the European Medicines Agency (EMA)'s robust registration procedure for biosimilar medicines and trust that biosimilar medicines are as effective and safe as the reference products.

The introduction of biosimilar medicines in Sweden increased access to biological treatment. Increasing access to biologics also gave an opportunity to treat patients with an earlier stage of disease, especially autoimmune diseases (for example in IBD).

In the case of the new biosimilar monoclonal antibody – trastuzumab, the Swedes wanted to build on their previous experience and great confidence from the medical society. The payer decided to organise tiered tenders, in which the medicine with the lowest price was the first on the list, but still the prescriber was left with the choice to use the reference medicine for his patient. Peer-to-peer communication between rheumatologists and gastroenterologists who already gained experience with biosimilar medicines, and less experienced oncologists took place. The payer decided to introduce complete benefit-sharing, where the entire savings coming from switching an originator to a cost-effective biosimilar medicine stayed with the budget holder. This turned out a powerful financial incentive to support the introduction of biosimilar medicines.

After the tender was won by a biosimilar trastuzumab (Jan 2019), clinicians in the hospitals switched patients who were previously on *intravenous (i.v.)* reference product. In addition, those patients who were on *subcutaneous (s.c.)* injections were switched to *i.v.* biosimilar products (infusions). As a result, the introduction of biosimilar trastuzumab dramatically decreased the costs of trastuzumab therapy. Moreover, patient access to treatment increased.

Robert Duncombe: Introducing Biosimilar medicines in oncology at The Christie NHS Foundation Trust

Professor Duncombe presented how the English National Health Service introduced biosimilar medicines into oncology therapy.

The national Cancer Vanguard program focused on the biosimilar adoption process¹ and assisted in the introduction of biosimilar medicines towards the patient community. A special template for pharmacists across

¹ <https://cancervanguard.nhs.uk/biosimilars-adoption/>

the UK (or toolkit) was developed. A Guidance tool describes how biosimilar medicines should be introduced in cancer therapy and supports the NHS in enhancing the clinical use of biosimilar medicines.

The tool describes a stepwise model of the biosimilar adoption process. Quantifying opportunity is one of the first steps to be made, showing how much budget might be wasted every day when denying the opportunity of the use of biosimilar medicine, as trastuzumab or rituximab. “Nationally every day we miss the opportunity, it will run into hundreds of thousands of pounds of missed opportunities.”

Important steps in the adoption process are:

- Perform a horizon scanning,
- Identify what the opportunity is,
- Identify what the service impact is,
- What the adoption process will be: (“big bang” – every patient switched on day 1 or a slow transition, starting from new patients, picking a date when every patient will be switched). The agreement on what the process of adoption will look like should be done in advance,
- The key is to engage patients’ groups in the process,
- Utilize ‘Medicines and Therapeutics Committees’ and be clear who in the organisation is in charge to make the final decision regarding the approach to be used,
- Discuss what sort of monitoring will be used? How do you build an evidence base to support the use?

Professor Duncombe presented what the adoption process looked like in the case of two biosimilar oncology medicines rituximab (i.v.) and trastuzumab (i.v.) at the Christie Hospital. In the case of rituximab, during the initial phase of the adoption process, two groups of patients were identified: patients on maintenance treatment (on subcutaneous formulations) and a second group, patients on intravenous treatment and acute treatment. For logistical and capacity issues, first group of patients on maintenance was not involved. The switch for patients on i.v. rituximab treatment started on 1st January 2019, when all new patients received treatment with biosimilar medicines and by February 2019 all patients on i.v. were on biosimilar medicine treatment.

For trastuzumab i.v., the plan was different. All new patients and all existing patients were planned to be switched to the biosimilar medicine. The “big bang” switch, when all patients receive biosimilar medicine was planned in November 2018.

Consultation with disease groups was held, building on the confidence with clinicians and education of the nursing and pharmacy staff. The ultimate decisions about the chosen approaches with those two medicines was made by the Medicine and Therapeutics Committee.

Clinician choice remained, provided they can generate evidence for using a different best value biologic. For pharmacists, the key was stability data. This is important because of dose-banding, in order not to generate waste.

Another key element to the choice was the development of the biosimilar market. In the UK, oncology pharmacists tried to bring different best valued biologics to clinical use in order to support the long-term sustainability of the biosimilar market, in line with the tender criteria. There might be a slight price difference, but it was important to send a very clear message to manufacturers to continue bringing biosimilar medicines to the market in the UK.

At the Christie hospital, an adoption process of biosimilar rituximab was straightforward, while it was more complicated in the case of trastuzumab. Some additional work was done to ensure a successful switch. Non-

medical prescribing pharmacists were in the lead, sending out letters to over 120 patients to inform them and give an opportunity to come back to the hospital pharmacy and discuss all potential concerns. There was also information about the switching process on Cancer Associations' websites, which provided independent advice to patients. Enhanced monitoring for switched patients was also implemented; the outcome of which will be presented later this year. In the end, the adoption process at Christie was very successful. Most patients were switched at the scheduled time. Almost all patients were switched to trastuzumab biosimilar by May 2019.

The economic benefit resulted in making the unaffordable affordable. The only way to invest in new cancer therapies is to optimise the use of existing ones and the key to it is to switch to biosimilar medicines where they are available.

Panel discussion on focusing on delivering continuous value to healthcare systems by undertaking a multi-stakeholder approach:

There are differences in the uptake across geographies.

Gustaf Befrits touched upon differences within Europe. Uptake is lower in southern Mediterranean countries and in countries with higher economic and budgetary constraints than northern European countries.

There are economic constraints involved in the use of biologics, even if we are talking about countries that can afford biologic treatment. Ultimately, patients are the ones who benefit from introducing cost-effective biosimilar medicines in terms of greater access.

Zorana Maravic pointed out how biosimilar medicines in IBD hugely increased the number of patients treated with biologics. The introduction of biosimilar medicines in oncology and colorectal cancer may give an opportunity to certain patients to receive treatment according to guidelines, given the inequality in access across Europe. It is important to involve patients in education about biosimilar medicines, policy making, open discussion.

Dr Paul Cornes brought in a global perspective, dividing the world into three different regions. **There are regions where access is already optimal and biosimilar medicines offer headroom to reinvest in innovation.** Cancer budgets need to have 7% inflation year per year to keep pace with pharmaceutical innovation. Therefore, if you can save 7% of your budget each year, without compromising safety or efficacy, you can maintain investment in innovation. **In the group of countries where access is limited by patient co-payment, we know that changing the amount of co-payment, even by a small amount, increases compliance with treatment;** we can even show a difference in the subsequent relapse rate of breast cancer when generic producers offer equivalent medicines at lower co-payments. **In regions where access to biologics is restricted at the moment, biosimilar medicines may offer the first opportunity to provide access to biologic treatment in those diseases (*de novo* access).** **Crucially, across these three different economic zones, biosimilar medicines benefit every single one.**

There are two roles that biosimilar medicines need to fulfil to be useful – they must be clinically similar in practice yet economically different for Health Systems and Payers. Concerns regarding the clinical similarity of biosimilar medicines that were raised during the first biosimilar era (from the first launch in 2006 to the introduction of monoclonal antibody biosimilar medicines a decade later) have now been resolved. The 2018 annual EU Biosimilar medicines Stakeholders Meeting at the European Commission was clear – European Approved biosimilar medicines are as safe to use as the reference medicine, can be used in indications where approval is gained from extrapolated data, can be switched as part of an annual medicine tender process and can be tracked

successfully in pharmacovigilance systems to ensure future safety. Now we are moving to new area, learning how to generate an economic difference with biosimilar medicines: “We need to share best practices and record the data, so that countries which are coming later in the game such as Australia, can pick and choose the best.”

Marnie Peterson elaborated on the three key areas where Australia could leverage on overseas experience: track and trace and traceability of biologics, patient centre care and economic argument. The very important part of the adoption process is to cooperate with patients’ groups.

Rob Duncombe highlighted that we need to move away from the idea biosimilar medicines are unsafe. It’s an effective and safe medicine. Whether we are talking about the US or UK, the ultimate drive is to tackle waste in pharmaceutical spending. Ultimately payers drive the uptake and healthcare budgets and payers ate the one to shape healthcare budgets.

Involvement of patients is key.

Dr Paul Cornes elaborated on bringing patients on board. In the UK there was a common belief this will be a stressful issue for patients and they will perceive a risk to biosimilar medicines oppose the switch. Risk however needs to be seen two ways:

Q. is there a risk to using biosimilar medicines? A. None seen so with multiple biosimilar medicines approved for 15 reference biologic therapies used over 13 years with >700M patient days’ exposure.

Q. is there a risk to NOT USING biosimilar medicines? A, clearly YES – in measurable financial toxicity to health systems and loss of health for patients through the subsequent lack of access to innovation in medicine.

The cost of delay of not using anti-inflammatory biosimilar medicines was 4 million GBP a week (5 million EUR per week). The cost of not using anti-inflammatory and oncology biosimilar medicines is more than one million pounds a day for the UK. For the early years of UK National Health Service use, biosimilar uptake was an initiative led by medical doctors, as it was initially in Sweden and it did not work well in either country measured by market uptake. After the decision was made that the switch needed to be led by pharmacists, the biosimilar story in the UK became success. ***The UK conclusion is that leadership and expert staffing resource is needed - it is important to have a person who is willing to meet patients to discuss this, to put their name and phone number on the letter sent to every patient and who is willing to receive their phone calls and address patient, nurse, pharmacist and physician concerns.*** As with the Swedish experience, financing this “cost of switching from a “gainshare” of the biosimilar savings.

Robert Duncombe explained that they recently performed a survey on trastuzumab with 100 ‘switched’ patients to share their experience. The response rate was around 30% and mainly positive, 70 % did not respond, which sends a message that most patients are not seeing this as a big issue.

There is an assumption among clinicians and pharmacists that patients are going to be upset when switched to a medicine that costs 50% less and you are the one saying it is as good. ***Patients also recognise that cancer medicines are expensive, and one way in which we can afford the next medicine in the line of treatment when the disease progresses is by accepting biosimilar medicines and understanding the opportunity of getting the new next best thing in cancer treatment if the disease progresses.*** Most patients understand this and most patients trust healthcare professionals to do the best thing in dialogue with them. We need to reassure them, both clinicians and pharmacists, that this is safe.

Zorana stressed the importance of patients being included in educational initiatives and policy making. Open discussions are needed. For patients to understand that biosimilar medicines are equally effective and safe and

that in return when their disease progresses patients have access to second- and third-line treatment is very important.

Moreover, savings from biosimilar medicines introduction can be reinvested in better health care system elements: more nurses, better facilities, other patients' support initiatives. ***It is important to indicate to both patients and clinicians how the money saved can be reinvested.*** It is not about saying this money will be saved, it is crucial to have an open discussion with all stakeholders on how to reinvest that money. All stakeholders want sustainability of healthcare systems.

Discussion on subcutaneous vs intravenous treatment

Dr Paul Cornes explained that like Stockholm, there was UK Health Service experience of balancing the time benefits of subcutaneous reference medicines against the financial impact of intravenous biosimilars because the totality of costs could be lower.² In Cardiff, rituximab intravenous formulation biosimilars were predicted to save one hospital £300,000 -335,000 a year over the subcutaneous reference biologic, however there was another aspect to consider for patients. Patients need to travel across town, through large urban areas to get lymphoma chemotherapy and the time-savings of subcutaneous drugs could be lost in overall travel times. Hence, the financial savings from biosimilars were used to work with patients and advocates to develop and staff infusion clinics closer to patients' homes. Feedback from patients was overwhelmingly positive: patients reported that they were pleased with their reduced travel times, the ease of parking at offsite units, and the prompt attention they received when arriving for their appointments. For Cardiff the initial benefit to haematology patients can now be expanded for other patients needing intravenous therapies – such as those with inflammatory disease as well.³

There is a bigger picture to be taken into consideration; biosimilars do not just drive like-for-like switches but can change practice patterns as well [for the better]. There is no doubt you can use biosimilar medicines to switch from subcutaneous to intravenous treatment while delivering overall patient benefit; we already have two examples from the UK and Sweden, but there are surely more examples to be shared.

Professor Rob Duncombe explained that in Manchester, they did not switch patients from subcutaneous to *i.v.*, since *s.c.* is administered in patients' own homes thereby reducing the burden of nurses, as homecare nurses can do more rapid *s.c.* injections. Naïve patients are introduced to IV treatment, since it is combined with chemotherapeutics that are applied intravenously as well.

There was a recent study published on adjuvant trastuzumab in patients with HER2 positive early breast cancer that supports a reduction of standard trastuzumab duration from 12 to 6 months and might change the need to

² Jang et al: PMU26: Budget Impact Analysis of Intravenous Biosimilars Compared with Intravenous Originators and Subcutaneous Products (<https://www.iqvia.com/-/media/iqvia/pdfs/isporbarcelona2018posters/november-12/budget-impact-analysis-of-intravenous-biosimilars-compared-with-intravenous-originators-and-subcutan.pdf?la=en&hash=2D02ABA3EC02181C25C18C0EE19EBA5C9F43AC4C>)

McBride A, Balu S, Campbell K, MacDonald K, Abraham I. Subcutaneous versus intravenous rituximab in non-Hodgkin lymphoma treated with R-CHOP: economic modelling for the US. Presented at the 60th Annual Meeting and Exposition of the American Society of Hematology; December 1-4, 2018; San Diego, California. Abstract 4776. ash.confex.com/ash/2018/webprogram/Paper113283.html

³ Bloodworth C, Myson V, Harries R, Lloyd C, Rowntree C. Creating off-site nurse led treatment units for administering chemotherapy to people with lymphoma nearer to their homes. Presented at the 58th Annual Scientific Meeting of the British Society for Haematology, April 16-18, 2018; Liverpool, United Kingdom. Abstract BSH18-OR-022. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.15226>

maintain patients on mono-therapy and the value of subcutaneous application will have to be reassessed in these types of setting.⁴

Approaching the topic more globally, ***there are parts of the world where there is a lack of well-trained healthcare personnel such as infusion nurses. For these areas, subcutaneous application makes a lot of sense and it is very encouraging that biosimilar medicines with subcutaneous delivery systems are being developed to help in these areas as well.***

Infrastructure where all stakeholders are aligned is key.

In Sweden the switch was slower because of the doctors' inability to see the patients, which was required in order to make a switch (receiving a new prescription). This shows the need for prescribing pharmacists as in the UK, who can take on that role and workload and manage the switch.

Both Stockholm and London have experienced the increased access that biosimilar medicines can bring; in both cities, biosimilar competition increased the use of filgrastim fivefold without increasing the cost.⁵ This gives us an indication of the real economic and healthcare impact of biosimilar medicines.

Biologic, including biosimilar medicines: what are key enablers to get penetration in markets like India, Malaysia ...

Both Sweden and the UK use Horizon scanning to give advance warning of biosimilar approval. When a market authorisation application is submitted to EMA, there is a 12-month- lead time before the medicine is approved and launched. This allows time to engage with stakeholders and plan biosimilar use optimisation ahead of the medicines entering the market. In Malaysia, the National Cancer Institute has been running education programmes for biosimilar medicines ahead of launches to prepare stakeholders while at the same time the medicine purchasing programme was reorganised with formulary sharing between hospitals to maximise the speed of access to best value medicines and deliver the greater cost-efficiency associated with high volume purchase tenders.

Building confidence of the stakeholders seems to be the key to gaining engagement with such a process.

However, looking beyond the EU experience, especially in Asia, we are facing different standards in biologics authorisation processes with a multiplicity of diverging standards and regulatory pathways. WHO has been very clear in their message: alignment on biosimilarity standards to a uniform WHO level is the safeguard for quality, safe and efficacious biosimilar medicines. They warn that without global standards, there will be a loss of confidence in biosimilar medicines as a class of medicines - risking the same mistake made with generic medicines, where the variability in enforced bioequivalence standards globally led to variation in the generic

⁴ PERSEPHONE study: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)30650-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30650-6/fulltext)

⁵ Gascón P, et al. Clinical experience with Zarzio® in Europe: what have we learned? *Support Care Cancer*. 2013;21:2925-2932]

[Antony Grosso, London Procurement Programme, 2012, quoted in Gascón P, et al. *Support Care Cancer*. 2013;21:2925-2932; 2.

Kashyap Thakrar. Biosimilar G-CSF: Implementation & lessons learnt. Centre for Medicines Optimisation UK. <http://centreformedicinesoptimisation.co.uk/files/Kash%20Thakrar%20Biosimiar%20-%20GCSF.pdf>. Accessed 10 June 2015.].

medicines quality and, as a consequence, a lack of physician and patient confidence.⁶ This could lead to biosimilar medicines being underused in exactly the middle-income countries where the health needs are the greatest.⁷

Main success factors:

- **Value to all the stakeholders needs to be tangible, create incentives such as benefit sharing.**
- **Continuous education of all the stakeholders needs to take place.**
- **Multidisciplinary approach in biosimilar adoption, involving physicians, pharmacists, nurses and patients in the process, but at the same time have a person, group or body who is a decision maker.**
- **Involvement of patients in open communication. As the patient is the end beneficiary it is important to put them in the centre of the discussion.**
- **All stakeholders are accountable, we have to align on the incentives and infrastructure.**

Biosimilar medicines bring greater access to treatment: we want more patients to be treated and that is what binds us all.

⁶ Tuan A. Nguyen et al. Generic medicines policies in the Asia Pacific region: ways forward. WHO South-East Asia Journal of Public Health. 2013;2(1):72-74

⁷ Report on the expert consultation on improving access to and use of similar biotherapeutic products. Geneva, 2–3 May 2017. Geneva: World Health Organization; 2017. Available from: http://www.who.int/medicines/access/biotherapeutics/FINAL_Report-improving-access-to-and-use-of-biotherapeutics_October2017.pdf [cited 2018 Feb 9].

Panel biographies



Stefan Hendriks

Global Head Biopharmaceuticals, Sandoz

Stefan Hendriks was appointed Global Head of Biopharmaceuticals at Sandoz in June 2018 and is part of the Sandoz Executive Committee. In this role, Stefan leads the organization that is responsible for the development and commercialization of biopharmaceuticals, including biosimilar medicines. Sandoz has eight biosimilar medicines approved in total, and under Stefan's guidance, has launched three biosimilar medicines in 2018 and continues to invest and expand the leading portfolio including into underserved therapy areas such as insulins. Stefan brings considerable experience in launch excellence and team leadership as well as brand and franchise management with over 20 years of serving in the pharmaceutical industry. He believes in unlocking the potential of each individual by focusing on a growth mindset, and creating an environment that is collaborative, curious and patient- and customer-centric. Prior to joining Sandoz Stefan worked at Bristol-Myers Squibb (BMS) where he held numerous country, regional and global roles across sales, marketing and general management for 15 years, and previously also worked for AstraZeneca. He has deep therapeutic area experience spanning immunology, oncology, endocrinology, virology, cardiovascular, and respiratory among others.



Gustaf Befrits

Coordinator Introduction of Biosimilar medicines, Stockholm County Council, Sweden

Gustaf is an administrator / health economist with the Stockholm County Council, which is the regional authority responsible for providing health care in the Stockholm region. He coordinates the introduction of biosimilar medicines in Stockholm. Before joining the Stockholm County Council four years ago he was a health economist with the TLV, the Swedish government agency responsible for reimbursement of pharmaceuticals for five years. Before joining TLV Gustaf worked as a health economist with Medtronic and before that as a health economist with Pfizer. Gustaf represented Sweden in the project group on "Market access and uptake of biosimilar medicines" which was part of the "Platform on access to medicines in Europe" under the European Commission. He was also health economist in the project team that performed a reimbursement review of TNF alpha inhibitors in Sweden. Gustaf holds a MSc in Health Economics from the Karolinska Institute in Stockholm and a BSc in Economics from the university of Lund, Sweden.



Marnie Peterson

Chief Executive Officer, Generic and Biosimilar Medicines Association, Australia

Marnie Peterson was appointed as Chief Executive Officer of the Australian Generic and Biosimilar Medicines Association (GBMA) in March 2018. Marnie also leads GBMA Education – the educational arm of GBMA, established to manage the Australian Government’s Educational Grant for Biosimilar Medicines, which was awarded to GBMA in April 2018. The purpose of the Grant is to increase confidence in the use of biosimilar brands of biological medicines that are listed on the Pharmaceutical Benefits Scheme (PBS). Through the increased use of biosimilar medicines, the objective is to support a competitive market for biological medicines via peer-to-peer health communication activities. With over 15 years in business management and marketing, Marnie’s pharmaceutical experience spans key executive roles in large generic pharma, company start-ups and business ownership. Managing commercial operations in each role, Marnie’s sales channel and marketing leadership extends across retail pharmacy, business development and hospital, including the delivery of end-to-end professional services programs for community pharmacy, corporate positioning, product development and go-to-market strategies. Marnie has predominantly spent her career in the Australian generic pharmaceutical sector, having worked for a range of key players including Apotex, Aspen generics, Actavis (Allergan) and Dr Reddy’s Laboratories.



Zorana Maravic

Director of Operations, Digestive Cancers Europe

Zorana Maravic is Director of Operations at Digestive Cancers Europe, previously EuropaColon, the first and only European digestive cancers patient umbrella organization. In her position, Zorana is responsible for the coordination and support of member groups, as well as establishing the relationship with new organisations in order to continue the network growth. As an experienced project manager, Zorana managed many of the projects undertaken by The Organisation, such as the Survey on the Unmet Needs of Patients Living with Metastatic Colorectal Cancer (mCRC) which recruited more than 800 patients with the results disclosed in several publications that Zorana authored; organised several Masterclass events, educational annual meetings for partner groups; developed various awareness campaigns including a few European Colorectal Cancer Awareness Campaigns (ECCAM); participated in various projects organised by pharmaceutical industry and independent consortia; worked closely with the Patient Advisory Committee (PAC) on the production of various educational materials to support patients. Zorana also acts as a public speaker. From 2016 until 2018, Zorana served as a Board Member of EuropaColon. Before working in the Not-For-Profit sector, Zorana worked for 10 years in the pharmaceutical industry, primarily in sales and marketing of innovative

oncology medicines as well as oncology clinical trials. Zorana holds a degree in molecular biology from the University of Belgrade, Serbia. In 2017, at the University of Sheffield, UK she gained an Executive MBA in Health Management.



Professor Rob Duncombe

Director of Pharmacy at The Christie NHS Foundation Trust in Manchester, UK

The Christie is one of the largest cancer centres in Europe treating patients from across the UK. The hospital recently opened the first NHS proton beam centre in the UK and is one of the first hospitals to offer CAR T therapy to patients. Professor Duncombe has a particular interest in medicines optimisation in cancer medicines, identifying ways to achieve the best value from the use of these medicines. In recent years Professor Duncombe has been at the forefront of delivering dose-banded chemotherapy in the UK and the introduction of biosimilar medicines in cancer.



Dr Paul Cornes

Oncologist, Comparative Outcomes Group, UK

Paul Cornes is an Oncologist from Bristol, UK. He is part of the steering group for the European School of Oncology Working Party on the Access to Innovation in Cancer Treatment. Paul was part of the team that developed and presented evidence to the Oncology Advisory medicines Committee of the FDA for the first successfully approved US biosimilar. He has been in the British Medical Journal's "Round Table" group on Biosimilar medicines as well as a faculty for the Medicine Information Association Meeting on Biosimilar medicines and has been on the panel for the EU Commission biosimilar medicines meeting in Brussels and chair of the biosimilar medicines programme for the World Cancer Congress for the UICC. In 2018 he wrote the book "Fast Facts: Biosimilars".