Ushering in the next wave of biosimilars by unlocking their potential [1]

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We are facing an extraordinary paradox in modern healthcare: the better it gets, the more difficult it becomes to offer it to everyone. Currently, our healthcare systems face steadily increasing costs, driven by a steadily growing and ageing population. The extra social and economic burden of the coronavirus pandemic has further compounded the access, equity and sustainability challenges facing healthcare systems.

Addressing these challenges in a balanced way will require a broad range of solutions, but one very powerful option has already been available for well over a decade: biosimilars. 15 years ago, Sandoz launched the world's first biosimilar. Since then, biosimilars have had a substantial positive impact on patient access and healthcare systems sustainability – but we still have a way to go to unlock their full potential.

Stepping up to this challenge, Sandoz recently collaborated with Reuters Events to bring together experts from patient organizations, healthcare (pharmacist), data science, and the pharmaceutical industry, for a live virtual discussion on the barriers to adoption of biosimilars worldwide and solutions that can improve access, affordability, and healthcare systems sustainability. Focus areas that emerged from the discussions included:

- Educating healthcare professionals and patients in a way that builds trust in and acceptance of biosimilars
- Implementing a multi-stakeholder (healthcare professionals, policymakers, patient organizations, and payers) approach to drive availability and adoption of biosimilars

Positioning biosimilars as an affordable option by refining reimbursement policies and incentivising use of biosimilars through mechanisms such as gain-sharin

- Establishing sustainable procurement practices that move away from the 'winner takes all' approach and encourage healthy competition amongst biologic manufacturers
- Implementing clearer regulatory pathways, following the example of the EMA, to fuel the growth and accessibility of biosimilars

The event comprised two panel discussions, separated by two interviews, the recordings of which can be accessed here:

Panel 1 [2]: 15 years of biosimilars in Europe – What lessons can we share?

Panel 2 [3]: Unlocking the potential of biosimilars worldwide

Europe leads the way

The first panel discussion focused on assessing the impact and lessons learnt from 15 years of biosimilars in Europe. When asked about the most significant impact biosimilars have had to date, Prof. Dr. Arnold G.

Vulto, Hospital Pharmacist n.p. Educator and Consultant on Biopharmaceuticals/Biosimilars, VuPEC said: ‘To put it simply, with biosimilars, the cost of medicines have gone down and access has increased exponentially. We have conducted considerable research on the impact of biosimilars and found that they have contributed towards creating a competitive market and released resources to pay for newer medicines. On the regulatory front, the EMA has done a great job by paving a clear regulatory pathway for biosimilars that turned out to be very safe, and this has really helped the growth of biosimilars in Europe.’

The patient perspective

Antonella Cardone, Director at the European Cancer Patient Coalition (the largest patient umbrella organization in Europe) said ‘Biosimilars present a necessary and timely opportunity for patients in Europe. Increased availability of effective biosimilars have directly translated into driving down the costs of biologic medicines which in turn has enabled more patients to access the medicines that they need.’

There is no doubt that biosimilars have had a transformative impact on patient lives, and we have seen some outstanding examples of this. In Germany, for instance, in 2015, rheumatoid arthritis patients had to wait 7.4 years to be treated with a biologic. Following the introduction of numerous biosimilars in this space, the waiting time is now down to 0.3 years.[i] In Spain, between 2009 and 2020, cancer and inflammatory therapy areas generated estimated cumulative savings of EUR 2.4 billion due to the entry of biosimilars.[ii, iii]

What lessons can we share? From top left to right: Prof. Dr. Arnold G. Vulto-Hospital Pharmacist n.p. Educator and

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Panel 1: 15 years of biosimilars in Europe : What lessons can we share? From top left to right: Prof. Dr. Arnold G. Vulto-Hospital Pharmacist n.p. Educator and Consultant on Biopharmaceuticals/Biosimilars, VuPEC, Antonella Cardone-Director, European Cancer Patient Coalition, Pierre Bourdage-Global Head Biopharmaceuticals, Sandoz, Sue Saville-Medical journalist & Moderator.

Fostering innovation

Another area of positive impact that is not often associated with biosimilars is innovation. ‘With biosimilar entry we create more incentive for innovation but beyond that there are incremental innovations that occur in the market which can be stability data for medications or a smaller needle gauge. We have seen a whole iteration of improvements where ultimately patients benefit and this also adds to healthcare sustainability,’ said Pierre Bourdage, Global Head Biopharmaceuticals, Sandoz.

Barriers to biosimilar acceptability—‘When is enough “enough”?’

‘While we see Europe as a success story, if you look closely, there have been disparities in access to biosimilars within Europe as well. In Poland for example, less than 1% of the oncology patients have access to biologics. This is a significant gap which needs to be addressed,’ said Rebecca Guntern, Head of Region Europe, Sandoz [Full interview here [4]]. Biosimilars are developed using a very rigorous and precise science and are approved by the same regulators who have approved the originator products. This is a fact which doctors and patients need to be aware of as misinformation and lack of awareness on biosimilars continue to pose hurdles to the adoption of biosimilars. ‘We have looked at 178 switch trials with 21,000 patients and no difference between biosimilars and their reference biologic was found.[iv] I think at some point, one really needs to ask when is enough “enough”?’ said Prof. Dr. Arnold G. Vulto.

Rebecca Guntern, Head of Region, Europe, Sandoz speaking about the role of biosimilars in supporting post-COVID

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Rebecca Guntern, Head of Region, Europe, Sandoz speaking about the role of biosimilars in supporting post-COVID-19 healthcare systems with Sue Saville

Taking a world view

The second panel discussion focused on highlighting measures that can help to unlock the full potential of biosimilars worldwide. ‘This is an exciting time, as we see more biologics coming off patent than before and in more therapeutic areas, but to get there we need to continue to fight misinformation and disparagement campaigns. We also need to refine reimbursement policies, procurement practices, and incentivize the use of biosimilars, making biosimilars a viable option for the healthcare community as well as for manufacturers,’ said Robert Spina, VP, Marketing, Market Access & Patient Services, Sandoz US.

‘In the US, there are over 80 biosimilars in the pipeline and these represent 45 reference biologics which we have found can translate into sales in excess of USD 80 billion in 2024 and savings exceeding USD 100 billion,’ said Christine Simmon, Senior Vice President of Policy & Strategic Alliances, Association for Accessible Medicines and Executive Director of the Biosimilars Council. ‘We have also seen the success of gain sharing models in several countries. In the United States, we don’t have that as yet, but we are advocating for a shared savings approach. Our data indicates that if the federal government shared the savings from biosimilars with prescribers, it would save more than USD 3 billion for seniors and more than USD 12 billion for taxpayers over the next 10 years. These are the kind of numbers that can help move the needle.’

Christine Simmon-SVP Policy & Strategic Alliances, Association for Accessible Medicines, Executive Director, Bio

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Panel 2: Unlocking the potential of biosimilars worldwide. From top left to right: Christine Simmon-SVP Policy & Strategic Alliances, Association for Accessible Medicines, Executive Director, Biosimilars Council, Claire Saxton-VP, Education and Outreach, Cancer Support Community, Murray Aitken-Executive Director, IQVIA Institute for Human Data Science, and Robert Spina-VP, Marketing, Market Access & Patient Services, Sandoz US

Ushering in a new wave of biosimilars

Sandoz is uniquely placed to lead the way for the next wave of biosimilars by fostering access and breaking down barriers. However, there are multiple factors that need to come together to create a favourable environment for the growth of biosimilars. Starting with patients and healthcare professionals, 'Education is key to unlocking the potential and benefits of biosimilars. Patients need to understand the benefits of biosimilars in a simple language and the onus of this, in most cases, lies in the hands of the HCPs,' said Claire Saxton, Vice President, Education and Outreach at the Cancer Support Community.

With looming healthcare debts and mounting concerns around addressing the backlog of treatments, the pandemic has pushed us to rethink the way we perceive, promote, and administer care. 'We have recently released a report from the IQVIA Institute which projects that over the next 5 years, the use of biosimilars can contribute USD 285 billion dollars of savings to payers. This is a significant sum and represents nearly double the amount that will be spent on COVID-19 vaccines which has been estimated to be USD 150 billion over the same time period,' said Murray Aitken, Executive Director, IQVIA Institute for Human Data Science. [link to full interview here [5]]

Biosimilars have demonstrated tangible benefits in the past 15 years. But more needs to be done around availability, accessibility, affordability, and acceptability to address barriers and create an environment which enables biosimilars to contribute to a truly sustainable healthcare system across the globe. Could this be achieved in the next 15 years? At Sandoz, we are committed to finding the answer and being a part of the solution.

Sandoz would like to thank all the speakers for their contributions that led to these stimulating and insightful conversations.

For more information about the journey of biosimilars over the past 15 years and what lies ahead, please visit our content hub: Unlock their potential – 15 years of biosimilars | Sandoz [6]

1. ProBiosimilars. New study shows: Rheumatoid patients have faster access to biological therapy since biosimilars exist. Available from: https://probiosimilars.de/presse/versorgung/studie-biologika-und-rheuma-patienten/ [7]. Last Accessed May 2021.
2. Biosimilars Saved Spain 2,400 Million Euros Between 2009 and 2020. Available at: https://www.eversana.com/2020/05/06/spain-biosimilar-savings/ [8]. Last accessed May 2021.
3. García-Goñi M, Río-Álvarez I, Carcedo D, Villacampa A. Budget Impact Analysis of Biosimilar Products in Spain in the Period 2009-2019. Pharmaceuticals (Basel). 2021 Apr 9;14(4):348. doi: 10.3390/ph14040348. PMID: 33918795; PMCID: PMC8069914.
4. Barbier L, Ebbers HC, Declerck P, Simoens S, Vulto AG, Huys I. The Efficacy, Safety, and Immunogenicity of Switching Between Reference Biopharmaceuticals and Biosimilars: A Systematic Review. Clin Pharmacol Ther. 2020 Oct;108(4):734-755. doi: 10.1002/cpt.1836. Epub 2020 Apr 30. PMID: 32236956; PMCID: PMC7540323.

Links
[1] https://sbx.sandoz.com/news/ushering-next-wave-biosimilars-unlocking-their-potential
[2] https://www.youtube.com/watch?v=_gHJtxniNGo
[3] https://www.youtube.com/watch?v=3SZswy64iEU
[4] https://www.youtube.com/watch?v=CE9I6V8LavE
[5] https://www.youtube.com/watch?v=ud7Fe1Znkjk
[6] https://www.sandoz.com/unlock-their-potential-15-years-biosimilars
[7] https://probiosimilars.de/presse/versorgung/studie-biologika-und-rheuma-patienten/

[8] https://www.eversana.com/2020/05/06/spain-biosimilar-savings/