DIA

Biosimilars Conference

Short Course: October 4 | Conference: October 5-6 | Virtual Event

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Overview

The Biosimilars Price Competition and Innovation Act (BCPIA) created a biosimilars approval pathway in the US with the goal of increasing access to safe, effective, and cost effective biological treatment options for patients. To date, significant progress has been made in the science and regulation of biosimilar development and approval but barriers still exist to a robust biosimilars market. The current ongoing challenges are legal complications to the launch of a biosimilar, the persistence of misinformation and disparagement, and delays in the creation of policies that increase patient access. The challenges have been and continue to be complex, interrelated, and best addressed by stakeholder collaboration, not only within the US but across global regions.

The development of biosimilars has been maintained by the prospect of cost savings to patients and possible improvement over the competition. To improve their market share, stakeholders are now focusing on streamlining biosimilars development, meeting ongoing manufacturing challenges, addressing pricing issues, and educating prescriber and patients on the benefits of biosimilars. At the DIA 2021 *Biosimilars Conference*, manufacturers, regulators, payers, prescribers, and patients will come together to discuss factors that influence biosimilar development and access and to share perspectives on what success and equilibrium will look like. They'll apply the newest thinking and relevant learnings from global regions to build strategies for continuing the growth of the biosimilars market and bringing these important biologic therapies-and cost savings - to patients.

Who Should Attend

Professionals involved in:

- Biosimilar/Biologic Pharmaceutical Research
- Biomedical Product Development and Manufacturing
- Regulatory Affairs
- Clinical and Nonclinical Research
- Biostatistics and Data Management
- Business Development
- Marketing and Commercialization for biosimilars
- Medical Communications/MSLs
- Patient Advocacy/Patient Support Programs
- Health and medical care across therapeutic disciplines
- Health Education
- Provision of prescription products
- Development and management of prescription product formularies
- Development and management of prescription benefit plans

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BIOSIMILAR DEVELOPMENT

Schedule At-A-Glance

All times listed are in EST

DAY ONE | MONDAY, OCTOBER 4

10:00AM-1:30PM	Short Course-Differentiating Your Biosimilar From the Crowd **This course requires an additional registration fee.*

DAY TWO | TUESDAY, OCTOBER 5

10:00-10:40AM	**Opening Remarks and Keynote Address**
10:40-11:00AM	Break / Visit the Virtual Exhibit Hall – Non CE
11:00AM-12:15PM	**Session 1:** Advances in Regulatory Thinking in Science and Knowledge
12:15-1:00AM	Break / Visit the Virtual Exhibit Hall – Non CE
1:00-2:15PM	**Session 2:** Switching and Interchangeability
2:15-2:45PM	Break / Visit the Virtual Exhibit Hall – Non CE
2:45-4:00PM	**Session 3:** How Different Is Too Different? Differentiation Opportunities and Challenges for Biosimilars

DAY THREE | WEDNESDAY, OCTOBER 6

9:30-10:00AM	Round Table Breakouts
10:00-11:15AM	**Welcome and Session 4:** Ask the Regulator
11:15-11:45AM	Break / Visit the Virtual Exhibit Hall – Non CE
11:45AM-1:00PM	**Session 5:** Biosimilars Role in Health Recovery, Disparities, and Equity
1:00-1:45PM	Break / Visit the Virtual Exhibit Hall – Non CE
1:45-3:00PM	**Session 6:** Payer Market Dynamics
3:00-3:30PM	Break / Visit the Virtual Exhibit Hall – Non CE
3:30-5:00PM	**Session 7:** US Biosimilar Market Policy and Closing Remarks
5:00PM	Conference Adjourns

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Discuss current developments in regulatory and scientific issues and their impact on development, manufacturing, access, and uptake of biosimilars and interchangeable products
- Discuss imperative and progress in streamlining biosimilar development
- Describe the impact of the approval of the first interchangeable biosimilar from a scientific and policy perspective
- Examine current prescriber and patient confidence and patterns of biosimilar use, and education efforts that have been successful in increasing literacy on these products
- Describe relevant international developments influencing patterns of biosimilar uptake globally
- Discuss new opportunities for product differentiation and utilization of regulatory flexibility
- Describe the status of biosimilar product development, availability, and uptake in the US

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This session is designated for up to 12.5 contact hours or 1.25 continuing education units (CEU's). Type of Activity: Knowledge

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*IACET CEUs are only available for the Short Course. Participants must attend the entire short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

October 4 Short Course 1: Differentiating Your Biosimilar From the Crowd: 3.25 contact hours or .325 CEUs Type of Activity: Knowledge, 0286-0000-21-075-L04-P

October 5 Day 1: Biosimilars Conference: 4.25 contact hours or .425 CEUs Type of Activity: Knowledge, 0286-0000-21-076-L04-P

October 6 Day 2: Biosimilars Conference: 5 contact hours or .5 CEUs Type of Activity: Knowledge, 0286-0000-21-077-L04-P

Continuing Education Credit and My Transcript

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This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

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DAY ONE | MONDAY, OCTOBER 4

All times listed are in EST

10:00AM-1:30PM

Short Course-Differentiating Your Biosimilar From the Crowd

**This course requires an additional registration fee.*

Cecil Nick, MS, FTOPRA, Vice President (Technical), Parexel Consulting, United Kingdom

Wyatt Gotbetter, Partner, Health Advances

A biosimilar must be similar to the innovator product, but there is some scope to differentiate your biosimilar from the crowd. Differentiation can be achieved through novel formulations and presentations such as an innovative delivery device. The EU regulatory system is more flexible than that of the US, allowing for the potential to introduce new routes of administration. Additional ways to make your biosimilar stand out are to build relationships with prescribers and offer support services to make life easier for prescribers, health care workers, and patients. Examples of support services are the provisioning of apps that help manage patient care and access to other information resources. In the US, a biosimilar approved as interchangeable can make your biosimilar stand out from the crowd. Interchangeability is most valuable for self-administered products supplied through community pharmacies but comes at a price of requiring a more extensive data package than a standard biosimilar. Finally, generating and publishing clinical data that serves to support prescriber confidence adds value. In this respect, education on the concepts of biosimilarity can also help gain market access.

At the conclusion of this session, participants should be able to:

- Formulate a strategy for differentiating your biosimilar from the crowd
- Develop a strong program to inform and support prescribers, health care workers and patients to safely use their medicine and best manage their condition
- Apply local regulatory opportunities to maximize the potential of your biosimilar while recognizing the limitations

DAY TWO | TUESDAY, OCTOBER 5

10:00-10:40AM

Opening Remarks and Keynote Address

Session Chair
Hillel Cohen, PhD, Executive Director, Scientific Affairs, Sandoz, Inc.

Keynote Speaker
Peter Stein, MD, Director, Office of New Drugs, CDER, FDA

10:40-11:00AM

Break

11:00AM-12:15PM

Session 1: Advances in Regulatory Thinking in Science and Knowledge

Session Co-Chairs

Cecil Nick, MS, FTOPRA, Vice President (Technical), PAREXEL Consulting, United Kingdom

Lu-Ning Cui, MD, PhD, Senior Clinical Evaluator, HPFB Health Canada

The concept of biosimilars is now almost two decades old with extensive experience on their development and use being amassed over that period. During this period analytical methodology for probing structure and comparing biological effects of biological medicines have significantly improved. Yet the regulatory approach to biosimilar approval has hardly changed. This session will explore whether there is still a need for large comparative efficacy and safety trials, and the extent to which comparative pharmacokinetic trials in healthy subjects could together with comprehensive physico-chemical and biological comparative data limit or eliminate the need for large patient studies.

One of the biggest challenges associated with limiting the amount of clinical data needed for approval, is faith that extrapolating structural, in vitro, pharmacokinetic and pharmacodynamic data to determine similarity in therapeutic effect is adequately robust and will not allow products with inferior efficacy -safety profile to be approved for marketing. Still, the current approach of requiring data in one indication and allowing extrapolation to other indications has met with resistance amongst some prescribers and patients. While these concerns are waning-education is a key element in support acceptance and appropriate use of biosimilars and this will be addressed in the second session. Finally, in view of the complexities defining regulatory requirements for biosimilar approval and the need to expand access to these life-changing and sometimes life-saving products-differently regulatory agencies may adopt different approaches to their approval and here WHO has played a key role in supporting regulatory decision making, which is the third presentation of this session.

At the conclusion of this session, participants should be able to:

- Develop and defend a strategy for streamlined development of a biosimilar
- Develop a strong program to inform and support prescribers, health care workers, and patients on the use of biosimilars
- Define an efficient, adequate, and effective program for the global development of biosimilars

Value and Need for Clinical Trials in the Development of Biosimilars

Christian Schneider, DrMed, Head of Biopharma Excellence and Chief Medical Officer (Biopharma) PharmaLex

Developing a Strong Program to Inform and Support Prescribers, Health Care Workers and Patients on Effective and Appropriate Use of Biosimilars

Sarah Crowley-Ikenberry, MA, Senior Communication Advisor, OTBB, OND, CDER, FDA

Globalizing Regulatory Thinking in Science and Knowledge in the Development of Biosimilar

Hye-Na Kang, DVM, Scientist, Technologies, Standards and Norms Team, Department of Essential Medicines and Health Products, World Health Organization (WHO), Switzerland

Panelist

Sarah Yim, MD, Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER, FDA

12:15-1:00PM

Break / Visit the Virtual Exhibit Hall – Non CE

1:00-2:15PM

Session 2: Switching and Interchangeability

Session Chair

Hillel Cohen, PhD, Executive Director, Scientific Affairs, Sandoz, Inc.

Switching from reference biologics to biosimilars is now accepted as a safe and effective practice. But the licensure of multiple biosimilars to the same reference product has led to the possibility of switching from one biosimilar to another biosimilar. We will review published studies that describe such biosimilar to biosimilar switches. In addition, the recent approval of the first interchangeable insulin by the FDA has opened the possibility of having more interchangeable biosimilar products becoming available in the US market. We will examine how interchangeability was and is being pursued for select biosimilar insulins.

At the conclusion of this session, participants should be able to:

- Discuss the current data supporting biosimilar-to-biosimilar switching
- Explain the rationale for interchangeability of biosimilar insulins

Biosimilar-to-Biosimilar Switching
Hillel Cohen, PhD, Executive Director, Scientific Affairs, Sandoz, Inc.

Interchangeability: From Insulins to mAB's
Sundar Ramanan, Vice President, Global Regulatory Affairs, Biocon Research Limited-SEZ Unit, India

2:15-2:45PM **Break / Visit the Virtual Exhibit Hall – Non CE**

2:45-4:00PM **Session 3:** How Different Is Too Different? Differentiation Opportunities and Challenges for Biosimilars

Session Chair
Leah Christl, PhD, Executive Director, Global Biosimilars Regulatory Affairs & Regulatory & R&D Policy, Amgen

Biosimilars are required to be similar to their reference product, but what does that truly mean? When competing for market share, it may be helpful to stand out from the crowd. But what is a helpful differentiation and when is different too different? Global regulatory frameworks for biosimilars vary in their prescriptive nature, leaving the door open for potential regulatory flexibility. This session will explore the opportunities for biosimilar manufacturers to differentiate their biosimilar while still meeting the regulatory requirements for biosimilarity.

At the conclusion of this session, participants should be able to:

- Distinguish biosimilar product differentiation opportunities within the global regulatory framework
- Evaluate development complexities and challenges when considering biosimilar differentiation

US and EU Framework and Differentiation Opportunities
Eva Temkin, JD, Partner, FDA, and Life Sciences, King & Spalding, LLP

Genevieve Michaux, JD, Regulatory Life Sciences Partner, King & Spalding, LLP, Belgium

Speaker
Irene Chan, PharmD, Deputy Director, Division of Medication Error Prevention and Analysis, OSE, CDER, FDA

DAY THREE | WEDNESDAY, OCTOBER 6

9:30-10:00AM **Round Table Breakouts**

Join fellow attendees for a chance to network and have a discussion surrounding topics of common interest. The moderator will kick off the conversation then we welcome the attendees to engage in a dialogue exchange and share knowledge with one another.

Global Harmonization
Gillian Woollett, DrSc, MA, Senior Vice President, Avalere Health

What do Patients Want to Hear About?
Stanton Mehr, Director of Content, Biosimilars Review & Report

Laura Wingate, Senior Vice President, Education, Support, and Advocacy, Crohn's & Colitis Foundation

Canadian Switching Programs
Nedzad Pojskic, PhD, MSc, Vice President, Pharmacy Benefits Management, Green Shield Canada

10:00-11:15AM **Welcome and Session 4:** Ask the Regulator

Session Chair

Emanuela Lacana, PhD, Deputy Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER, FDA

During this session regulators from around the world will provide updates on new initiatives, guidance, and regulatory approaches pertinent to their jurisdiction. Following the presentations, panelists will address questions from the audience.

At the conclusion of this session, participants should be able to:

- Define updated regulatory requirements discussed by the speakers
- Compare regulatory requirements across jurisdictions and identify commonalities and differences
- Discuss the impact of updates described by speakers on global biosimilar development programs

Speakers
Patricia Aprea, MD, Director, Evaluation and Control of Biologicals/Research, ANMAT, Argentina

Lu-Ning Cui, MD, PhD, Senior Clinical Evaluator, Health Canada, Canada

Hye-Na Kang, **DVM**, Scientist, Technologies, Standards and Norms Team Department of Essential Medicines and Health Products, World Health Organization, Switzerland

Emily Gebbia, JD, Policy Staff Director, CDER, FDA

Elena Wolff-Holz, MD, PhD, Chair, Biosimilar Medicinal Products Working Party (BMWP) of CHMP; Assessor, Paul-Ehrlich Institute

11:15-11:45AM — **Break / Visit the Virtual Exhibit Hall – Non CE**

11:45AM-1:00PM — **Session 5:** Biosimilars Role in Health Recovery, Disparities, and Equity

Session Chair
Julie Marechal-Jamil, MSc, Director, Biosimilars Policy and Science, Medicines for Europe, Belgium

Optimal patient care and Healthcare systems sustainability are both part of a difficult equation to manage, and recent months have showed that resilience needs to be further built in to ensure equity in access to care. There are many roads to efficiency in healthcare. One of them involves optimal use of biosimilar medicines. There is growing evidence that biosimilar medicines use has already allowed smart re-investment of healthcare funds into: broader access (more patients treated), earlier access in the treatment course (lifting cost-related restrictions) but also funding of new therapeutics or supportive care, or healthcare staff, infrastructure or services.

At the conclusion of this session, participants should be able to:

- Explain the value of biosimilar medicines for healthcare & patient care beyond price competition
- Illustrate - with concrete examples - the biosimilar experience in creating broader, earlier, and future access to biologic medicines and healthcare
- Compare and contrast the opportunities depending on the therapy area and patient treatment course (i.e. cancer, diabetes)

Living with Cancer in the US-Opportunities for Better Access Equity and Affordability of Care
Pam Traxel, Senior Vice President, American Cancer Society Cancer Action Network

Living with Diabetes in the US – Opportunities for Better Access Equity and Affordability of Care
Erika Emerson, Chief Policy Officer, Diabetes Leadership Council and Diabetes Patient Advocacy Coalition

Revealing the Value Biosimilar Medicines
Paul Cornes, MD, Oncologist, Bristol Oncology Centre, United Kingdom

1:00-1:45PM — **Break / Visit the Virtual Exhibit Hall – Non CE**

1:45-3:00PM — **Session 6:** Payer Market Dynamics

Session Chair
Stanton Mehr, Director of Content, Biosimilars Review & Report

Over the next 24 months, the biosimilar industry will be entering a crucial phase in the US. Payers have played a leading role in determining whether biosimilars are covered and influencing their uptake. This session will address how payers are considering anticipated biosimilar launches for adalimumab, insulin, and ranibizumab.

At the conclusion of this session, participants should be able to:

- Describe the factors that payers may consider when deciding which adalimumab biosimilar(s) or the reference product they will place on formulary
- Recognize the benefits or risks that covering a biosimilar under the pharmacy benefit (vs the medical benefit) can pose for payers
- Assess how payers will approach potential interchangeability designations among these critical biosimilar categories

Preparing for Humira Biosimilars
Luke Greenwalt, MBA, Vice President, Market Access Center of Excellence, IQVIA

Payer Aspects: What It Would Mean to Cover Biosimilars Under the Pharmacy vs. Medical Benefit
James Kenney, MBA, RPh, Princpal, JTKenney, LLC

The Potential Impact on Payers of Biosimilar Insulin
Stephanie Ho, PharmD, Pharmacist Evidence Analyst, Kaiser Permanente

Improving Hospital and Health System Uptake of Biosimilars
Steven Lucio, PharmD, Senior Principal, Center for Pharmacy Practice Excellence, Vizient Inc.

3:00-3:30PM — **Break / Visit the Virtual Exhibit Hall – Non CE**

3:30-5:00PM — **Session 7:** US Biosimilar Market Policy and Closing Remarks

Session Co-Chairs
Juliana Reed, MS, Vice President, Corporate Affairs, Global I & I and Biosimilars Lead, Pfizer, Inc.

Tiffany Fletcher, MA, Head of Global Biosimilar Policy and Access, Viatris

Biologics are the single largest driver of prescription drug spending –making up 40% of US drug spending but accounting for just 2% of prescriptions filled. The first biosimilar became available to patients in the U.S. in 2015, and since then the FDA has approved 30 biosimilars and 20 are currently available to patients. With estimated launch prices at an average 30% lower than their originator products, biosimilars could play an essential role in the US healthcare system, both in terms of expanding access to biologic therapies, providing patient and physician choice, and addressing the healthcare budget. IQVIA estimates that the expanded availability of biosimilars will save $100 billion in U.S. drug costs over five years. In order to achieve the full savings potential of biosimilars, this session will explore policy solutions to support greater adoption of biosimilars in the US.

At the conclusion of this session, participants should be able to:

- Describe the current US biologics/biosimilars market
- Identify specific market barriers to greater biosimilar adoption
- Evaluate policy solutions to support patient, provider, and payer uptake of biosimilars
- Assess the benefits that policy incentives for biosimilars can bring to the US healthcare system and to patients

Speakers
Anna Hyde, Vice President, Arthritis Foundation

Ted Okon, MBA, Executive Director, Community Oncology Alliance

Margaret Rehayem, Vice President, National Alliance of Healthcare Purchaser Coalitions

Meaghan Smith, Executive Director, Biosimilars Forum

5:00PM — **Conference Adjourns**