Ask the Expert: Exploring Issues with Biosimilars in Health Systems

Presented as a Live Webinar
Thursday, March 20, 2014
1:00 p.m. – 2:00 p.m. EDT

Planned and conducted by ASHP Advantage and
supported by an educational donation provided by Amgen.

W E B I N A R I N F O R M A T I O N

How do I register?

Go to http://www.ashpadvantagemedia.com/biosims/expert.php and click on the **Register** button. After you submit your information, you will be e-mailed computer and audio information.

What is a live webinar?

A live webinar brings the presentation to you – at your work place, in your home, through a staff in-service program. You listen to the speaker presentation in "real time" as you watch the slides on the screen. You will have the opportunity to ask the speaker questions at the end of the program. Please join the conference at least 5 minutes before the scheduled start time for important announcements.

How do I process my Continuing Education (CE) credit?

Continuing pharmacy education for this activity will be processed on ASHP's new eLearning system and reported directly to CPE Monitor. After completion of the live webinar, you will process your CPE and print your statement of credit online at http://elearning.ashp.org/my-activities. To process your CPE, you will need the enrollment code that will be announced at the end of the webinar.

View full CE processing instructions

What if I would like to arrange for my colleagues to participate in this webinar as a group?

One person serving as the group coordinator should register for the webinar. That group coordinator will receive an e-mail confirmation with instructions for joining the webinar. A few minutes before the webinar begins, the group coordinator should launch the webinar link. Once the webinar has been activated, the coordinator will have the option to open the audio via VoIP (Voice Over IP) on the webinar toolbar or use a touch tone phone with the provided dial-in information. At the conclusion of the activity, the group coordinator will complete a brief online evaluation and report the number of participants at that site. Each participant will process his or her individual continuing education statement online.

What do I need in order to participate in the webinar?

1. Computer with internet access and basic system requirements. When you register, the webinar system will assess your system to ensure compatibility.
2. Telephone to dial the toll-free number and listen to the presentation (if you choose not to use Voice Over IP [VoIP] via your computer).

Webinar System Requirements

Be sure to view the webinar system requirements for Windows, Mac, iOS, and Android prior to the activity.

A C T I V I T Y F A C U L T Y

James G. Stevenson, Pharm.D., FASHP, Activity Chair
Chief Pharmacy Officer
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Professor and Associate Dean for Clinical Sciences
Chair, Department of Clinical, Social, and Administrative Sciences
University of Michigan College of Pharmacy
Ann Arbor, Michigan

James G. Stevenson, Pharm.D., FASHP, is Chief Pharmacy Officer at the University of Michigan Health System, as well as Professor and Associate Dean for the Department of Clinical Sciences at the University of Michigan College of Pharmacy.

Dr. Stevenson received his Bachelor of Science and Doctor of Pharmacy degrees from Wayne State University in Detroit, Michigan. He then joined the faculty at the West Virginia University School of Pharmacy in Morgantown.

Dr. Stevenson's previous appointments include Director of Pharmaceutical Services at West Virginia University Hospitals, Director of Pharmacy Services at Detroit Receiving Hospital and University Health Center, Director of the Graduate Program in Health Systems Pharmacy Management in the Wayne State University College of Pharmacy, and Executive Director of Pharmacy Services for the Detroit Medical Center.

He is a Fellow of the American Society of Health-System Pharmacists (ASHP) and received the Award for Distinguished Leadership in Health-System Pharmacy Practice at the 48th ASHP Midyear Clinical Meeting, December 2013. The Award for Distinguished Leadership in Health-System Pharmacy Practice recognizes the contributions of practitioners who have achieved excellence in health-system pharmacy practice leadership. Dr. Stevenson has also been recognized as Pharmacist of the Year by both the Michigan Society of Health-System Pharmacists and the Michigan Pharmacists Association. He has also been honored with the Distinguished Alumnus Award by the Wayne State University College of Pharmacy and the Joseph Oddis Leadership Award by the Michigan Society of Health-System Pharmacists. He recently completed a term of service on the ASHP Board of Directors and received the John W. Webb Lecture Award in 2010. In 2012, Dr. Stevenson was appointed to the Michigan Board of Pharmacy.

Dr. Stevenson's major research interests include pharmacy practice management, pharmacoeconomics, pharmacy informatics, and medication safety.

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The faculty listed below report the following relationships pertinent to this activity:

- James G. Stevenson, Pharm.D., FASHP, has served as an advisory board member and speaker for Amgen.

The following faculty and planners report no relationships pertinent to this activity:

- Susan R. Dombrowski, M.S., B.S.Pharm.
- Erika Thomas, M.B.A., B.S.Pharm.

ASHP staff have no relevant financial relationships to disclose.

Additional Educational Opportunities on this Topic

Did you miss the live symposium "Biosimilars: An update on Scientific, Legislative, and Safety Issues" held in December 2013 at the ASHP Midyear Clinical Meeting & Exhibition in Orlando?

It's now available on-demand at:

www.ashpadvantage.com/biosims

Ask the Expert: Exploring Issues with Biosimilars in Health Systems

ACTIVITY OVERVIEW

Biosimilars are biological medicines that are "highly similar" to an innovator biological product, but due to their complexity, are not the same as the innovator product. There are unique scientific, legislative, and safety issues associated with biosimilars.

The content for the live webinar is based on questions raised by participants in a recent educational symposium on this topic. Time for questions and answers from the webinar audience will be provided at the end of the presentation.

LEARNING OBJECTIVES

At the conclusion of this application-based educational activity, participants should be able to

- Compare and identify important differences between biosimilars and innovator products.
- Discuss considerations for incorporating biosimilars into the health-system formulary.

CONTINUING EDUCATION ACCREDITATION

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1.0 hour (0.1 CEU) of continuing pharmacy education credit (ACPE activity # 0204-0000-14-462-L03-P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education (CPE) credit following the activity.

Complete instructions for processing CE can be found on the last page of this handout.

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Learning Objectives

- Compare and identify important differences between biosimilars and innovator products.
- Discuss considerations for incorporating biosimilars into the health-system formulary.

What is a Biosimilar?

- "Copy" of a commercially available therapeutic biologic agent (reference)
- Approved via an abbreviated pathway
- Exhibits "highly similar" efficacy and safety compared with reference product
- Interchangeable biosimilar
  - Can switch back and forth between biosimilar and reference with no clinical consequences
  - Appropriate for substitution without consulting the prescriber

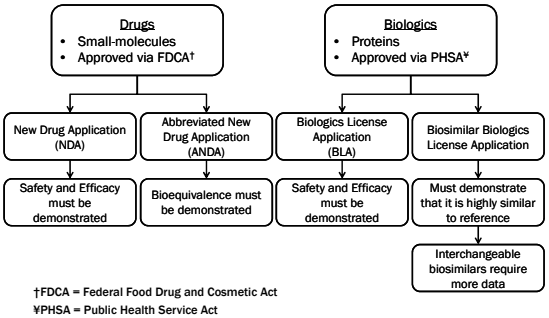
Weise M et al. *Nat Biotechnol*. 2011; 29:690-3.
Zelenetz AD et al. *J Natl Compr Canc Netw*. 2011; 9(Suppl 4):S1–S22.

Biosimilar Legislation

- Subtitle: Biologics Price Competition and Innovation Act (BPCI) of 2009 created an abbreviated FDA approval pathway for biosimilars
- Before BPCI, there was no abbreviated pathway for FDA approval of copies of biologics
- According to the FDA, "drugs" are different from "biologics"

U.S. Food and Drug Administration. Implementation of the Biologics Price Competition and Innovation Act of 2009. March 10, 2011. (URL in ref list).

Pathways for Approval in the USA



†FDCA = Federal Food Drug and Cosmetic Act
¥PHSA = Public Health Service Act

See enlargement, p. 14

Question

What are some of the key differences between biosimilars and small molecule generics?

Differences Between Small Chemical Drugs and Biologics

- Small Chemicals
  - Synthesized from chemicals through controlled and predictable processes
  - Low molecular weight compounds
- Biologics
  - Proteins derived from genetically engineered living cells
  - More complex molecules
  - More complex production process
  - Large molecular weight proteins
  - Larger variation from lot to lot in end product given production from living systems
    - Potential for immunogenicity

Zelenetz AD et al. J Natl Compr Canc Netw. 2011; 9(Suppl 4):S1–S22.

Similarities and Differences vs. Reference Product

Biosimilar Product Specification	Comparison with Reference
Formulation	May be different
Delivery device/container	May be different
Routes of administration	May obtain licensure for fewer than all routes of administration for which reference product is licensed
Conditions of use	May obtain licensure for fewer than all conditions of use for which reference product is licensed
Strength	Must be the same

U.S. Food and Drug Administration. Guidance for industry on biosimilars: Q&As regarding implementation of the BPCI Act of 2009: questions and answers part I. February 9, 2012. (URL in ref list.)

Biosimilars

- Copy of a biologic medicine, not produced by innovator company
- Similar in physicochemical characteristics, efficacy, and safety, based on a comprehensive review
- Considered "highly similar" to the reference product
- NOT a generic equivalent (bioequivalent)
- Approved through an abbreviated regulatory process

Demonstrating Biosimilarity: General Principles

- The clinical efficacy and safety of the biologic molecule has already been demonstrated (i.e., by the innovator)
- The biosimilar sponsor only requires evidence that the candidate biosimilar is not significantly different from the reference product.
  - Goal is not to replicate unnecessary clinical trials
  - Smaller scale direct comparisons and extrapolation of data

U.S. Food and Drug Administration. Draft guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. February 2013. (URL in ref list).

Question

How is the manufacturing process different for biosimilars, interchangeable biosimilars, and full Biologics License Application (BLA) copies?

Biologics Have a Complex Manufacturing Process

1. Clone DNA into vector
2. Transfer DNA into host cell for expression
3. Cell expansion
4. Cell production in bioreactors
5. Recovery of biologic
   - Filtration
   - Centrifugation
6. Purification through chromatography
7. Characterization and stability

Mellstedt H, et al. *Ann Oncol* 2008; 19:411-419.

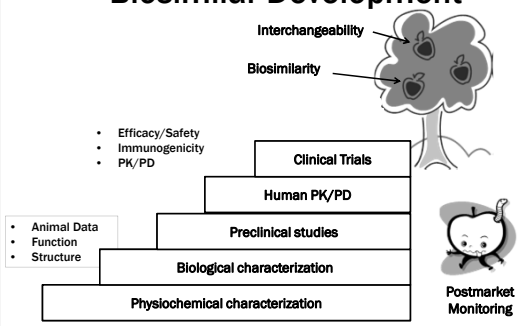
Manufacturing May Be Similar, But Not Identical Among Manufacturers[1,2]

Operational Step	Variable Unique to Each Manufacturer	Potential Product Differences
Cell selection[1]	Expression cassette, placement in genome, cell line[1]	Molecular structure • Amino acid modification, glycosylation[1]
Cell expansion[1]	Cell line, growth media, method of expansion[1]	
Cell production in bioreactors[1]	Cell line, growth media, bioreactor conditions[1]	Biological activity • Measured using biological systems[2]
Recover through filtration or centrifugation[1]	Operating conditions[1]	
Purification through chromatography[1]	Binding and elution conditions[1]	Content • Isoforms, impurities, aggregates[1,3]
Characterisation and stability[1]	Methods, reagents, reference standards[1]	Final dosage form • Excipients, strength, container[2]

1. Mellstedt H, et al. *Ann Oncol*. 2008;19:411-419; 2. U.S. Food and Drug Administration. Draft guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. February 2012. URL in ref list. 3. Sharma BG. Eur J Hosp Pharm Pract. 2007; 13:54-6.

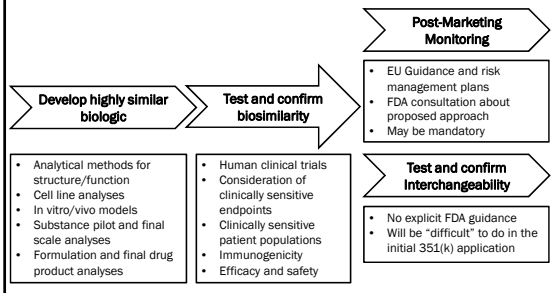
See enlargement, p. 14

Biosimilar Development



Adapted from: McCamish M et al. *Clin Pharmacol Ther*. 2012; 91:405-17.

Biosimilar Development Approach



Adapted from: McCaSusan 2/20/2014

U.S. Food and Drug Administration. Guidance for industry on biosimilars: Q & As regarding implementation of the BPCI Act of 2009: questions and answers part I. February 9, 2012. URL in ref list.

See enlargement, p. 15

Question

Under the new law, how long is the exclusivity period for an innovator biologic?

Generic drugs have 6 months of exclusivity. Do biosimilars have a similar provision and if so, is it justified?

BPCI Act Provisions

- Requirements can vary for abbreviated approval process
- 12 years of exclusivity for innovator biologic products (6 month pediatric indication extension)
- Three categories
  - Biosimilar
  - Interchangeable biosimilar
  - Full BPCI-approved biologic

Audience Response Question

How many biosimilars do you anticipate will receive FDA approval in the next 5 years?

a. None
b. 1 or 2
c. 3-4
c. 5-10
d. >10

Potential Patent Expirations by 2020

- Epoetin alfa
- Filgrastim
- Pegfilgrastim
- Adalimumab
- Insulin aspart/ Insulin glargine
- Rituximab
- Infliximab
- Bevacizumab
- Trastuzumab

I believe it is unlikely that we will see any "interchangeable biosimilars" designated by the FDA during the first 4-5 years. However, I believe many health systems will designate products as therapeutically interchangeable and payers will encourage use of biosimilars.

Question

What are the issues surrounding biosimilar naming and what do various organizations recommend?

Nomenclature Issues

- Naming should allow the practitioner to quickly understand the relationship between the biosimilar and reference product
- Use of same name for multiple sources of product may be problematic for pharmacovigilance purposes
- EU naming
  - Allows the biosimilar to use the same nonproprietary name as reference product
  - Can lead to unmonitored substitution
  - UK has advised physicians to prescribe by brand name to prevent automatic substitution
- Can the use of codes help pharmacovigilance efforts?

Megerlin F et al. *Health Aff (Millwood).* 2013; 32(10):1803-10.

FDA Guidance: Postmarketing Monitoring (for Safety)

- Important to assure safety
  - Consider risks seen in reference product
  - Are there any new safety concerns?
  - Population-based assessments give larger N to identify rare safety concerns
  - PV might be mandatory for some products
- Biosimilar manufacturers should work with FDA to discuss approach

U.S. Food and Drug Administration. Guidance for industry on biosimilars: Q & As regarding implementation of the BPCI Act of 2009: questions and answers part I. February 9, 2012. URL in ref list.

Organizational Positions

- Generic Pharmaceutical Association – no justification for use of different International Nonproprietary Name (INN)
- PhRMA/Biotechnology Industry Organization (BIO) – products are not exact equivalents, so they shouldn't share the same INN.
- WHO – still being discussed but some version of a nonproprietary name plus some prefix or suffix is being considered
- Bipartisan group of legislators/payers - different names would create unnecessary confusion for doctors and patients, possibly triggering medical errors. Also, any such federal regulation would needlessly interfere with state laws on generic substitution

My Prediction

- Use of similar INN with a distinguishing prefix or suffix to differentiate products for pharmacovigilence purposes
- Botulinum toxin example
  - Onabotulinum toxin A
  - Abobotulinum toxin A
  - Rimabotulinum toxin B
- Epoetin example
  - Epoetin alfa
  - Epoetin beta
  - Epoetin theta
  - Epoetin gamma
  - Epoetin zeta

Question

What is the rationale behind all of the state proposals to limit the interchange of biosimilars?

What determines interchangeability – federal or state law, local institution, or practitioner?

Audience Response Question

Do you support recent state proposals to limit the interchange of biosimilars?

a. Yes
b. No
c. I'm not sure

State Proposals Are Driven By BPCI Act…Definitions (from BPCI):

- "Biosimilar" means:
  - "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and "no clinically meaningful differences" in terms of "safety, purity and potency"
- "Interchangeable" biosimilar means a biosimilar that:
  - "can be expected to produce the same clinical result" in "any given patient," and (if administered more than once) has no greater risk "in terms of safety or diminished efficacy" than the reference product

Interchangeable biosimilar is a designation from the FDA. NOT having this designation doesn't preclude payers or health systems creating their own rules using a formulary or drug benefit design system

U.S. Congress. Sections 7001-7003 (Biologics Price Competition and Innovation Act of 2009) of the Patient Protection and Affordable Care Act (Public Law 111-148). URL in ref list.

State Proposals Are Driven by BPCI Act

- As FDA continues work on implementing BPCI Act, states have been considering proposals to restrict substitution of biologic medications that are deemed similar/ interchangeable, but have not been cleared for marketing by FDA as literally being "generic" in the FDCA sense
- Supporters of state proposals believe the ultimate decision on substitution should be left to the patient's prescribing physician
- Opponents believe state proposals are restrictive/ inconsistent with forthcoming national standards, and will increase the cost of healthcare unnecessarily

National Conference of State Legislatures. Pro and con arguments on substitution. (URL in ref list); Generic Pharmaceutical Association. State initiatives. (URL in ref list); Pollack A. *New York Times*. January 28, 2013. (URL in ref list).

Common Elements in State Bills

- Definitions from BPCI/FDA
  - Biological Product
  - Biosimilar
  - Interchangeable biosimilar (so far, FDA has received no biosimilar applications, therefore no interchangeability requests either)

Common Elements in State Bills

- Prescriber preference
- Patient choice: notification of patient/prescriber if substitution occurs
- Labeling
- Recordkeeping (years required vary by state)
- Pricing (not more than product originally prescribed)
- List of substitutable products (State Board of Pharmacy)

Where Is This Going?..Considerations

- Veto of California bill may have slowed down legislative activity- California a bellwether; more negotiation may take place nationally between supporters/opponents
- Is there a need to reconcile biosimilar substitution with existing state laws on substitution of generic drugs (although very existence of BPCI Act underscores the fact that similar and interchangeable biologics are not classified as "generic")?
- Are Federal/State roles in practice of medicine and pharmacy affected by BPCI Act or further FDA guidance? (Reminiscent of compounding issue)

How Can Pharmacists Prepare?

- Familiarize yourself with applicable laws
- Some laws are being adopted with sunset clauses and may expire in whole or in part before applications/ determinations occur
- Closely follow your State Board of Pharmacy's guidance
- Pharmacy/healthcare organizations are a good resource for updates

Question

What will be the primary considerations by health systems in determining formulary inclusion and interchangeability of biologics and biosimilars?

Pharmacy Practice Implications

- Generic substitution may not be appropriate for biosimilars, but therapeutic equivalence programs are likely within health systems
- Pharmacists will need to lead evaluation of biosimilars for formulary inclusion
  - Range of indications
  - Therapeutic equivalence
  - Process for therapeutic interchange within health systems
  - Information systems to enable pharmacovigilance

Considerations for Formulary Inclusion of Biosimilars

Efficacy/Safety	Manufacturer Considerations	Product Considerations	Hospital and Patient Factors
• Clinical data • Range of indications • Immunogenicity concerns • Potential for therapeutic interchange • Number of similar agents on formulary • Pharmaco-vigilance requirements	• Supply reliability • History of drug shortages • Supply chain security • Anti-counterfeit measures • Patient assistance programs • Reimbursement support	• Product packaging and labeling • Bedside bar coding • Compatibility with CSTDs*, robotics • Product preparation and administration • Storage requirements	• Economic considerations ✓ Hospital ✓ Patient • Payer policies • Transitions of care • IT and medication system changes • Educational requirements

* CSTDs = closed system transfer devices

See enlargement, p. 15

Major Challenges for P&T Committees with Biosimilars

- If approved for a specific indication, will use be allowed for other indications?
- Decisions surrounding product naming critical to provide clarity when ordering, prevent errors, ensure traceability, and facilitate PV
- Evaluation of overall economic impact of use of biosimilars
  - Combined inpatient and outpatient impact
  - Challenges of portfolio pricing
  - Impact on patient out-of-pocket expense

Major Challenges for P&T Committees with Biosimilars

- How many "similar" products to carry on the formulary
- How to manage transitions of care
  - Desire to minimize switching
    - Reduced chance for error
    - Avoid potential immunogenicity problems
  - Analogy with generic immunosuppressants in transplant recipients?

Audience Response Question

Would it be reasonable to consider the use of the reference product after a patient has started therapy with a biosimilar?

a. No, because safety cannot be assured
b. Yes, because FDA has deemed the biosimilar sufficiently similar to the reference product
c. Yes, but only if FDA deems it interchangeable
d. I'm not sure

Therapeutic Interchange for Biosimilars

- FDA categorization as "interchangeable biosimilar" or "biosimilar"
  - Potential impact of state laws on implementation
- Prepare a monograph for the biosimilar and policy for review by the P&T committee
  - Describe the data comparing the biosimilar with reference product
  - Expected outcomes
    - Clinical: efficacy, safety, immunogenicity
    - Economic
- Many examples:
  - Non-biologics: analgesic, anti-infective, cardiovascular, CNS, GI
  - Biologics: Insulins, IVIG, erythropoietic-stimulating proteins

ASHP. *Am J Health-Syst Pharm.* 2008; 65:1272–83

Postmarketing Surveillance

- Pharmacovigilance activities essential to further assess ongoing safety and immunogenicity
- Major responsibility for pharmacists and practicing clinicians to identify and report potential safety/immunogenicity concerns
- Naming convention for biosimilars is a concern for effective reporting (must be able to trace adverse effects to a specific product)
- Importance of configuring IT systems to be able to track specific products

Recommendations For Biosimilars in Health Systems

- Utilize existing formulary system and processes to evaluate for formulary inclusion
- Carefully consider scope of indications for use
- Conduct sophisticated economic analysis, considering costs, reimbursement, and patient impact
- Plan for therapeutic equivalence and guided-use policy and processes
- Consider processes for transitions of care
- Prepare IT systems to facilitate effective pharmacovigilance programs
- Meet educational needs of patients and providers

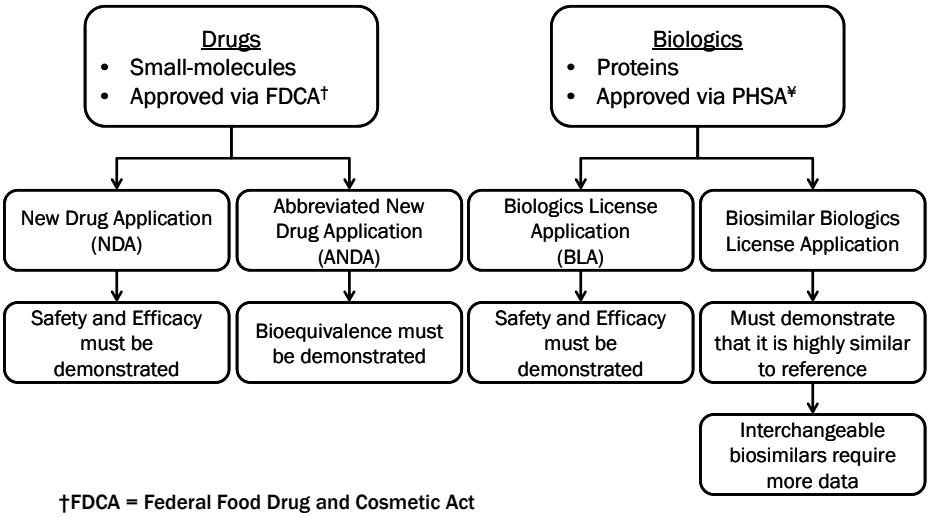
Resources for Pharmacists

- ASHP Resource Center on Biosimilars
  - http://www.ashp.org/menu/PracticePolicy/ResourceCenters/EmergingSciences/Biosimilars.aspx
- ASHP Advantage Site
  - http://www.ashpadvantage.com/biosimcentral/
- American Journal of Managed Care Resource Center
  - http://www.ajmc.com/resource-center/biosimilars
- Lucio SD, Stevenson JG, Hoffman JM. Biosimilars: Implications for health-system pharmacists. *Am J Health-Syst Pharm.* 2013; 70:2004-17.

Conclusion

- Biosimilars present significant opportunities and challenges for pharmacists managing formularies and patient care
- A framework for biosimilar introduction has existed in Europe and is being defined in the US
- Pharmacists must educate themselves to be prepared to play leadership roles in the safe and appropriate introduction of biosimilars into health systems
- Existing principles of sound formulary management can be applied to biosimilars

Pathways for Approval in the USA



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Cell expansion[1]	Cell line, growth media, method of expansion[1]
Cell production in bioreactors[1]	Cell line, growth media, bioreactor conditions[1]
Recover through filtration or centrifugation[1]	Operating conditions[1]
Purification through chromatography[1]	Binding and elution conditions[1]
Characterisation and stability[1]	Methods, reagents, reference standards[1]

Potential Product Differences

Molecular structure
- Amino acid modification, glycosylation[1]

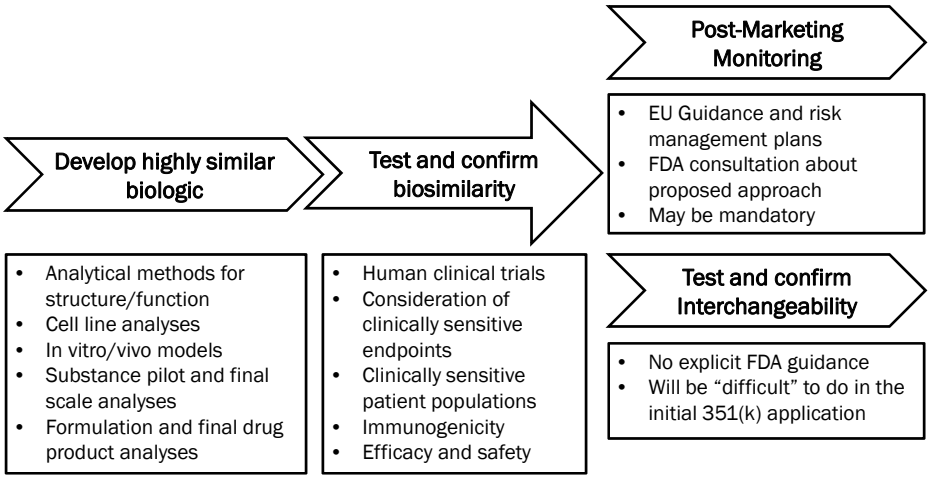
Biological activity
- Measured using biological systems[2]

Content
- Isoforms, impurities, aggregates[1,3]

Final dosage form
- Excipients, strength, container[2]

1. **Mellstedt H, et al. *Ann Oncol*. 2008;19:411-419; 2. U.S. Food and Drug Administration. Draft guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. February 2012. URL in ref list. 3. Sharma BG. Eur J Hosp Pharm Pract. 2007; 13:54-6.**

Biosimilar Development Approach



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REFERENCES AND SELECTED READINGS

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S E L F - A S S E S S M E N T Q U E S T I O N S

1. Compared with the reference product, biosimilars:
   a. May have a different formulation
   b. May have a different strength
   c. Must be licensed for the same routes of administration
   d. May be licensed for more conditions of use

2. Which of the following organizations proposes to resolve nomenclature issues for biosimilars by using a nonproprietary name plus a prefix or suffix?
   a. Biotechnology Industry Organization
   b. Generic Pharmaceutical Association
   c. Pharmaceutical Research and Manufacturers of America
   d. World Health Organization

3. Opponents of state proposals to restrict substitution of biologic medications that are deemed similar or interchangeable argue that the restrictions would :
   a. Reduce errors
   b. Increase costs
   c. Interfere with prescriber autonomy
   d. Pose a safety risk

4. Which of the following are the greatest concerns in switching from a reference product to a biosimilar at transitions of care?
   a. Medication errors and high cost
   b. Medication errors and patient nonadherence
   c. Immunogenicity and medication errors
   d. Adverse effects and patient nonadherence

Answers

1. a
2. d
3. b
4. c

Instructions for Processing CE Credit with Enrollment Code

Pharmacists and Technicians:

All ACPE accredited activities which are processed on the eLearning site will be reported directly to CPE Monitor. To claim pharmacy credit, you must have your NABP e-profile ID, birth month, and birth day. If you do not have an NABP e-Profile ID, go to www.MyCPEMonitor.net for information and application. Please follow the instructions below to process your CPE credit for this activity.

1. The **ASHP eLearning** site allows participants to obtain statements of continuing education conveniently and immediately using any computer with an internet connection. Type the following link into your web browser to access the e-Learning site: **http://elearning.ashp.org/my-activities**

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3. Once logged in to the site, enter the enrollment code for this activity in the field provided and click **Redeem**.
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4. The title of this activity should now appear in a pop-up box on your screen. Click on the **Go** button or the **activity title.**

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6. Available credit(s) will appear beneath the completed required activities. Look for your profession in the list of available credits and click the appropriate **Claim** button. You might have to click to see more credit options if you don't see your profession listed.
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8. After successfully claiming credit, you may print your statement of credit by clicking on **Print**. If you require a reprint of a statement of credit, you can return here at any time to print a duplicate. Please note that for CPE credit, printed statements may not be necessary because your credit will be reported directly to CPE Monitor.

Date of Activity	Activity Title	Enrollment Code	Credit Hours
March 20, 2014	Ask the Expert: Exploring Issues with Biosimilars in Health Systems	_ _ _ _ _	1.0

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