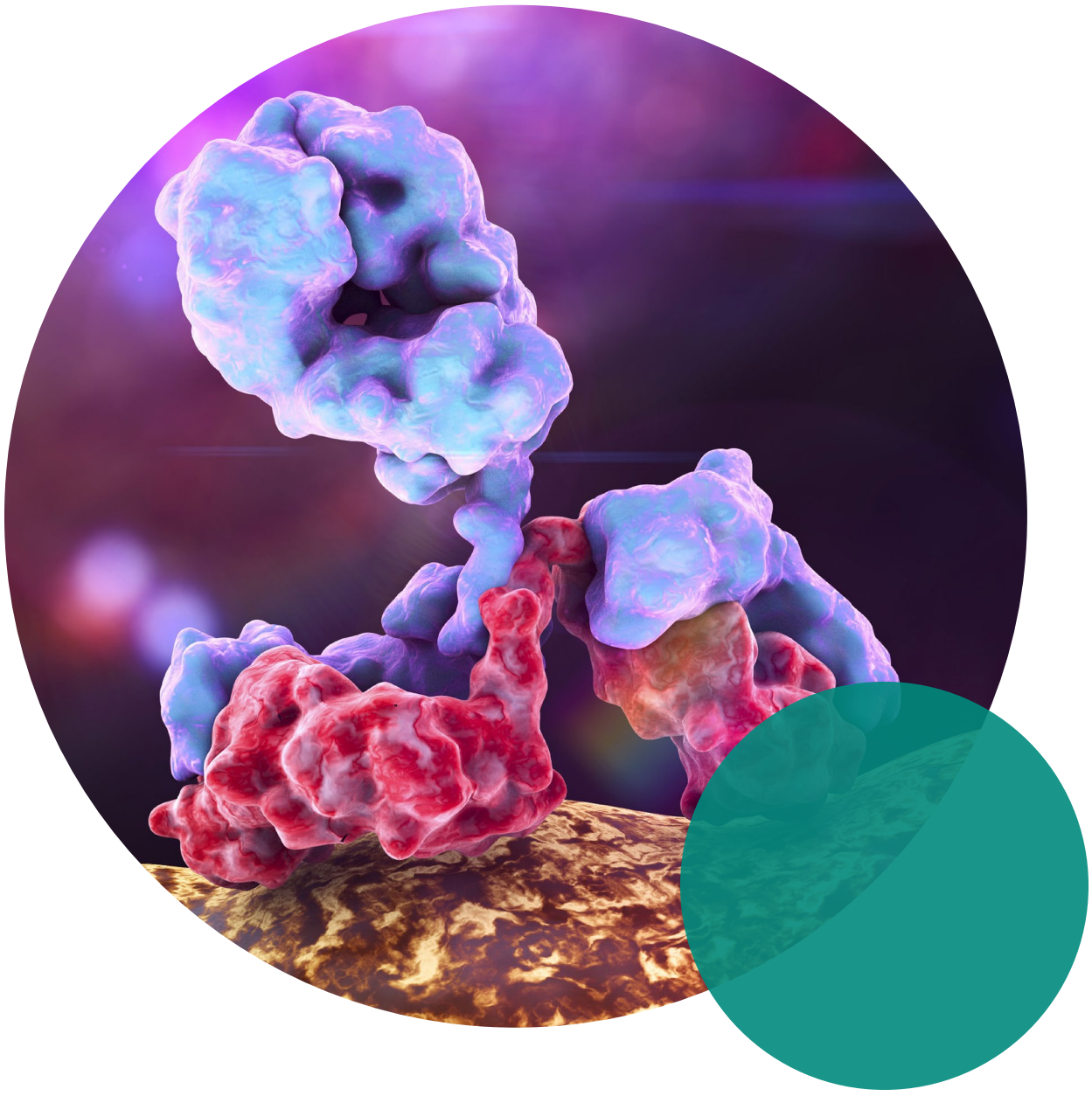
# Making Sense of the Biosimilars Market

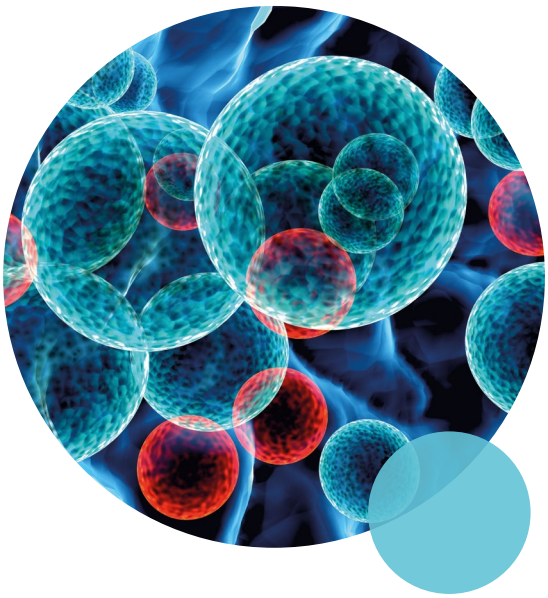
## Strategies and Recommendations to Achieve Optimal Market Access



ICONplc.com/biosimilars
ICONplc.com/commercialisation

## Contents





## Introduction

Biosimilars are generally expected to offer a competitive price advantage to appeal to healthcare organisations and payers which make them an attractive business opportunity. A critical component of market access planning is the ability to communicate an integrated proposition that will alleviate any potential concerns and optimise perceptions of value. Biosimilar developers need to prepare a comprehensive market access strategy. It is important that commercialisation success factors are integrated into the strategy at an early stage and are revisited often during development decision making. In preparation for market entry, biosimilar developers must offer a value proposition for their product that resonates with payers and other stakeholders who are influential in access and reimbursement related decisions. This whitepaper provides an introduction into key regulatory and development concerns for sponsors, including a discussion of the factors that affect biosimilar uptake for the United States and Europe and recommendations to address these issues.

## What Are Biosimilars?

A biosimilar is a highly similar version of an already authorised original biological medicinal product (reference medicine). Because biosimilars are made in living organisms, minor structural differences may exist between a biosimilar and its reference medicine, but these differences are not clinically meaningful [1, 2]. Biosimilars are important because they encourage competition and lower prices, thereby enhancing patient access to biologic treatments and relieving pressure on healthcare budgets [3, 4].

## Regulatory Approvals in Major Markets

Since the European Medicines Agency (EMA) approved the first biosimilar, Sandoz's Omnitrope (somatropin) in 2006, the EU has pioneered the regulation of biosimilars. Over the last decade, the EU has approved the highest number of biosimilars worldwide, amassing considerable experience of their use and safety (Table 1) [1]. Japan has also embraced biosimilars relatively quickly – in March 2009, the Ministry of Health, Labour and Welfare published biosimilar guidelines based on those of the EMA, and the Pharmaceuticals and Medical Devices Agency (PMDA) approved Japan's first biosimilar, Sandoz's Somatropin BS, only three months later [5].

The US, on the other hand, has lagged with respect to biosimilar adoption. An abbreviated pathway for biosimilars was not established in the US until March 2010 with the passage of the Biologics Price Competition and Innovation Act of 2009 [6]. For this reason, and because the Food and Drug Administration (FDA) did not release finalized biosimilar guidance until April 2015, the first US biosimilar, Sandoz's Zarxio (filgrastim-sndz), did not launch until September 2015 [7]. Despite a slow start, the US has caught up with Japan in terms of the number of approved biosimilars, and the FDA has released additional guidance on a range of topics related to biosimilar development.

**Table 1. Biosimilars approved in major markets, by class (as of November 2018)**

| Class of Biosimilar | Europe (EMA) | Japan (PMDA) | USA (FDA) |
|---|---|---|---|
| Anti-TNF (e.g. infliximab) | 14 | 4 | 7 |
| Erythropoietin-stimulating agent (e.g. epoetin alfa) | 5 | 2 | 1 |
| Granulocyte colony-stimulating factor (e.g. filgrastim) | 9 | 3 | 4 |
| Human growth hormone (e.g. somatropin) | 1 | 1 | 0* |
| Immune biologic (e.g. rituximab**) | 6 | 0 | 0 |
| Insulin (e.g. insulin glargine) | 4 | 2 | 0* |
| Oncology monoclonal antibody (e.g. bevacizumab) | 11 | 2 | 2 |
| Other (e.g. follitropin alfa) | 6 | 0 | 0 |
| **Total number of approved biosimilars** | **50**** | **14** | **14** |

*In the US, hormones are regulated as drugs under the Food, Drug, and Cosmetic Act, not biological products under the Public Health Service Act; as a result, non-originator insulins are not biosimilars (8). **Rituximab is an immune biologic and an oncology monoclonal antibody; as such, the total number of approved biosimilars may not equal the sum of approvals across classes EMA, European Medicines Agency; FDA, Food and Drug Administration; PMDA, Pharmaceuticals and Medical Devices Agency

## Biosimilar Development

The aim of biosimilar development is to demonstrate biosimilarity – high similarity in terms of structure, biological activity, efficacy, safety and immunogenicity – based on comprehensive comparability studies with the reference medicine. By demonstrating biosimilarity, a biosimilar can rely on experience gained with the reference medicine, thereby avoiding repetition of clinical trials (i.e. if a biosimilar is highly similar to a reference medicine in one therapeutic indication, safety and efficacy data may be extrapolated to other indications for which the reference medicine is already approved) [1,2].

## Health Technology Assessment for Biosimilars in Europe

In the EU and the European Economic Area, health technology assessment (HTA) is the responsibility of individual member states. In most cases, EMA-approved biosimilars are not appraised by HTA bodies (Table 2), and automatically receive the same level of reimbursement as the reference medicine (provided they are less expensive). Depending on the market in question, sponsors may have to submit a cost-minimisation model to demonstrate the level of saving that could potentially be realised through use of their biosimilar. If the reference medicine is not reimbursed, biosimilar sponsors may have to submit a full submission to an HTA body, which may involve a cost-effectiveness analysis [9].

**Table 2. UK HTA bodies' positions on biosimilars (as of November 2018)**

| HTA Body | Position on Biosimilars |
|---|---|
| **All Wales Medicines Strategy Group (AWMSG) (10)** | – AWMSG does not normally appraise biosimilars.<br>– Existing HTA advice for reference medicines published by AWMSG or the National Institute for Health and Care Excellence (NICE) automatically applies for biosimilar medicines licensed for the same indication and in the same population as the reference medicine.<br>– In the absence of advice for the reference medicine, the biosimilar is not endorsed for use within NHS Wales. |
| **National Institute for Health and Care Excellence (NICE)** | – NICE assesses biosimilars alongside their reference medicines in multiple technology appraisal guidance; to date, it has published guidance for human growth hormone [11], erythropoiesis-stimulating agents [12], and TNF-alpha inhibitors [13-16].<br>– All relevant published guidance that includes the reference medicine also applies to biosimilars at the time they are made available for use in the NHS. A funding direction will apply to a new biosimilar if the active drug substance has already been recommended by NICE [17].<br>– NICE can decide to apply guidance to other relevant licensed biosimilars that are subsequently approved.<br>– For biosimilars that are not included in a technology appraisal, if NICE thinks there needs to be a review of the evidence, it may produce an 'evidence summary: new medicine' [17]. |
| **Scottish Medicines Consortium (SMC)** | – Since May 2015, the SMC has not routinely assessed biosimilars on the basis of a full submission (i.e. biosimilars are considered 'out of remit' where the reference medicine has been accepted by SMC/Healthcare Improvement Scotland [HIS] for the same indications and in the same population or was initially licensed and available prior to 31 January 2002) [18].<br>– Full submissions are required for indications/populations where the reference medicine is not recommended by SMC/HIS [18]. |

## Factors Affecting Biosimilar Uptake

For payers, the key factor affecting biosimilar uptake is the level of discount between a biosimilar and its reference medicine. According to research conducted by the Patented Medicine Prices Review Board in 2017, median list price discounts for biosimilars in OECD markets range from 13% to 34%, which is relatively modest in comparison to generic drugs [19]. It is worth noting, however, that this estimate excludes procurement discounts agreed at national and/or regional levels which can significantly increase a biosimilar's overall discount [20].

Physicians, on the other hand, are mainly concerned about the efficacy, safety and tolerability of biosimilars [21-23]. Immunogenicity is a key safety concern, as evidenced by the fact that, in rare cases, antibodies generated against exogenous erythropoietin may elicit hypersensitivity reactions which can lead to pure red cell aplasia [24, 25]. Efficacy, safety and tolerability are also key concerns for patients, particularly in markets where medicines are fully reimbursed. As a result, in settings where incentives do not exist for prescribers, biosimilars (particularly those that are first-in-class) are disproportionally prescribed to patients who are initiating treatment. This is an important barrier to biosimilar uptake, and is exacerbated by the fact that automatic pharmacy-level substitution (the practice of dispensing a biosimilar instead of the reference medicine by a pharmacist without consultation from a prescribing physician) is currently prohibited in most markets (the FDA has issued draft guidance on biosimilar interchangeability [26], but as of November 2018, no FDA-approved biosimilars have achieved this designation). To address these concerns, regulatory bodies and payer organisations have published educational materials for patients and healthcare professionals [1-3, 27, 28], and biosimilar marketers have made stakeholder education a key element of their promotional campaigns [29, 30].

## Payer Strategies To Drive Biosimilar Uptake

### Europe

In Europe, biologics are often procured through tenders, and biosimilar companies are often the winners because they offer the lowest prices. Many European markets conduct regional tenders using a non-exclusive approach whereby the reference medicine is procured alongside the winning biosimilar. Under this system, the winning biosimilar is typically prescribed to new patients, and the reference medicine is reserved for patients who are continuing treatment. Biosimilar uptake is generally much higher in markets which conduct national tenders using an exclusive approach, as is the case in some of the Nordic countries. In Norway, for example, biosimilars represent more than 90% of infliximab and etanercept sales [4]. Unsurprisingly, this approach to tendering is also associated with the greatest discounts; for example, in 2016, the winner of the Norwegian infliximab tender, Hospira, offered a 61% discount relative to the reference medicine, Remicade. More recently, AbbVie is rumoured to have won the 2018 Danish national tender for adalimumab by offering an 80% discount on the list price of its reference medicine, Humira [31].

Financial incentives and penalties for physicians are important strategies used by European payers to increase biosimilar uptake. For example, some hospital trusts in London have implemented gain-share agreements which allow clinical commissioning groups to share 50% of the cost-savings attributed to biosimilars [32-35], a strategy which has resulted in high rates of switching [35]. In Germany, regional prescribing quotas for erythropoietin-stimulating agents, infliximab, and etanercept biosimilars have been agreed between the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung). Quotas increase each year and physicians who fail to meet a quota receive a financial penalty (the average quota for 2018 is 40%) [36].

### United States

In the US, biosimilar uptake is determined by the formulary status of biosimilars and reference medicines. In 2016, UnitedHealth and CVS Health announced that they were excluding branded versions of insulin glargine and Neupogen (filgrastim) from their 2017 formularies in favour of Basaglar (insulin glargine) and Zarxio, respectively (Basaglar is not classed as a biosimilar because in the US, hormones are regulated as drugs under the Federal Food, Drug, and Cosmetic Act, not biological products under the Public Health Service Act) [8, 37, 38]. Despite these changes, biosimilar uptake in the US has lagged behind that of Europe. FDA Commissioner Scott Gottlieb has attributed poor biosimilar uptake in the US to misalignment of incentives and lack of competition within the drug supply chain, obscure pricing, and failure to pass savings from rebates back to patients [39].

## Originator Company Strategies to Defend Against Biosimilar Uptake

In general, an originator company has three options to defend itself against biosimilar competition:

1. Develop a next-generation branded medicine to supersede the reference medicine;
2. Alter the reference medicine to differentiate it from competing biosimilars, and;
3. Make the market access environment unfavourable for competing biosimilars (e.g. through price cuts, supply deals, and/or legal protections).

Development of a next-generation branded medicine can involve molecular modification of the reference medicine to improve its clinical profile and/or dosing. Examples of this approach include Amgen's Neulasta, a pegylated version of filgrastim which is longer-lasting due to decreased renal clearance [40], and Roche's Gazyva, a glycoengineered monoclonal antibody which induces antibody-dependent cell-mediated cytotoxicity more effectively than Rituxan/MabThera (rituximab) [41]. Originator companies can also develop an innovative delivery device or system for their reference medicine. For Neulasta, Amgen has developed the Onpro on-body injector which eliminates the need for patients to revisit the clinic and improves treatment adherence [42].

A less risky but potentially effective strategy for defending against biosimilar uptake is to modify the reference medicine to differentiate it from competing biosimilars and/or increase its cost-effectiveness. This approach has been utilised by Roche for the development of subcutaneous (SC) formulations of MabThera and Herceptin (trastuzumab). These formulations can be administered rapidly (SC MabThera is administered over five minutes whereas the IV formulation is administered over two and a half hours) resulting in reduced utilisation of hospital resources and greater convenience for patients. SC Herceptin is also covered by a new patent which extends exclusivity until 2030 [43].

A more common strategy, however, is to offer discounts and/or rebates for the reference medicine. Price cuts typically supersede biosimilar entry but may precede loss of exclusivity if, for example, an originator company enters into a long-term supply deal. This was the case for Janssen-Cilag in New Zealand: in exchange for a 34% reduction in Remicade's ex-manufacturer price, plus an additional confidential rebate, Remicade became the only available infliximab in District Health Board hospitals from March 2015 until February 2020 [44].

Last but not least, an originator company can leverage intellectual property and legal protections to delay biosimilar entry. AbbVie has used this approach to great effect to protect its highest selling drug, Humira (adalimumab); through a series of settlements, it has delayed biosimilar entry in the US to 2023 [45-48]. Amgen has also used this approach to protect its rheumatoid arthritis drug, Enbrel (etanercept), which was due to undergo patent expiry in October 2012; Enbrel is now protected until 2028 thanks to U.S. Patent No. 8,063,182 which was issued in November 2011 despite having been filed more than a decade earlier [49]. Sanofi also used legislation to defend Lantus (insulin glargine) against Basaglar: by filing a patent infringement lawsuit against Eli Lilly and Boehringer Ingelheim in January 2014, Sanofi was able to trigger an automatic 30-month stay under the Hatch-Waxman act [50] which, coupled with a subsequent patent settlement agreed in September 2015, delayed Basaglar's launch until December 2016. This gave Sanofi extra time to promote Toujeo, its next-generation insulin glargine [51].

## Recommendations for Biosimilar Developers

To achieve optimal market access, it is imperative that biosimilar developers have the resources to develop and manufacture biosimilars at scale, with sufficient throughput, and at a competitive price (this is particularly important for companies that will participate in European tenders where pricing pressure is generally highest). In terms of clinical development, studies must be designed to support regulatory assessments in target markets (e.g. evaluation against locally-sourced reference medicines in appropriate indications and populations). Guidelines covering biosimilar development are available in major markets and many emerging markets, but companies will need to stay abreast of updates as the industry matures.

Biosimilar developers must also have a strong grasp of competitive, patent, and regulatory landscapes to ensure that they fully understand the size of the opportunity and potential barriers to uptake. Companies that can anticipate and respond dynamically to developments will have a competitive advantage over 'laggards'. Biosimilar developers with insufficient expertise and/or resources should consider forming strategically-favourable partnerships, as has been the case for companies such as Samsung Bioepis, a joint venture between Samsung Biologics and Biogen, and Celltrion, the latter of which has partnered with an array of companies to streamline distribution and marketing of its biosimilars.

Finally, biosimilar developers should, where possible, aim to achieve a first-mover advantage over their competitors. The biosimilar market is still relatively young and many high-selling biologic brands have yet to undergo loss of exclusivity; as such, a tremendous opportunity still exists for biosimilar developers to gain a share of the global biologic market which is currently valued at over $240 billion [52].

## Authors

**Tom Hutchings**
**Consultant, Global Pricing & Market Access**

As a consulant within ICON's pricing and market access practice, Tom advises biosimilar clients about the impact of genericisation on payers' willingness to pay for novel brands. Prior to joining ICON, he was a biosimilars analyst at Decision Resources Group, covering products in immunology, oncology, nephrology, and endocrinology. At Adelphi Values, a market access consultancy, he helped develop the European pricing strategy for Bemfola, a biosimilar infertility treatment. Tom has an MSc in Molecular Medicine and a BSc (Hons) in Biology, both from Imperial College London.

**Petra Roos**
**Senior Director, Clinical Project Management**

Petra Roos, MSc. PMP, Sr. Director, Project Management Biosimilars and Biotech. Petra heads up the ICON Biosimilar project management group. Petra is a Project Management Institute certified project management practitioner with more than 20 years of experience including extensive experience in Biosimilar Development.

## References


1. European Medicines Agency, European Commission. Biosimilars in the EU - Information guide for healthcare professionals. 2017.
2. U.S. Food & Drug Administration (FDA). What is a Biosimilar?
3. Australian Government Department of Health. Why are biosimilar medicines important? 2017 [Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-why-are-biosimilar-medicines-important.
4. Norwegian Medicines Agency. Regulation of biosimilars and success factors for uptake in clinical practice. 2018.
5. Generics and Biosimilars Initiative (GaBi). Biosimilars approved in Japan 2018 [Available from: http://gabionline.net/Biosimilars/General/Biosimilars-approved-in-Japan.
6. U.S. Food & Drug Administration (FDA). Implementation of the Biologics Price Competition and Innovation Act of 2009 2016 [Available from: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm.
7. Sandoz launches ZarxioTM (filgrastim-sndz), the first biosimilar in the United States [press release]. 2015.
8. U.S. Food & Drug Administration (FDA). Frequently Asked Questions About Therapeutic Biological Products 2015 [Available from: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm.
9. Canadian Agency for Drugs and Technologies in Health (CADTH). Biosimilars — Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook. 2018.
10. All Wales Medicines Strategy Group (AWMSG). Position Statement For Biosimilar Medicines [Available from: http://www.awmsg.org/awmsgonline/grabber?resId=File%2F2963.
11. National Institute for Health and Care Excellence (NICE). Human growth hormone (somatropin) for the treatment of growth failure in children 2010 [Available from: https://www.nice.org.uk/guidance/ta188.
12. National Institute for Health and Care Excellence (NICE). Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy 2014 [Available from: https://www.nice.org.uk/guidance/ta323.
13. National Institute for Health and Care Excellence (NICE). TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis 2016 [Available from: https://www.nice.org.uk/guidance/ta383.
14. National Institute for Health and Care Excellence (NICE). Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people 2017 [Available from: https://www.nice.org.uk/guidance/ta455.
15. National Institute for Health and Care Excellence (NICE). Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed 2016 [Available from: https://www.nice.org.uk/guidance/ta375.
16. National Institute for Health and Care Excellence (NICE). Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy 2015 [Available from: https://www.nice.org.uk/guidance/ta329.
17. National Institute for Health and Care Excellence (NICE). Biosimilar medicines – NICE's approach 2017 [Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/technology-appraisal-guidance/Biosimilars-information-for-the-public-April-2017.pdf.
18. Scottish Medicines Consortium (SMC). Biosimilar medicines 2015 [Available from: https://www.scottishmedicines.org.uk/media/2836/biosimilar-medicines.pdf.
19. Patented Medicine Prices Review Board. Potential Savings From Biosimilars In Canada. 2017.
20. Regional Drug & Therapeutics Centre (RDTC), Northern Treatment Advisory Group. Etanercept Biosimilar (Benepali®). 2016.
21. Cohen H, Beydoun D, Chien D, Lessor T, McCabe D, Muenzberg M, et al. Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians. Adv Ther. 2017;33(12):2160-72.
22. Tanabe K, Sugimoto N, Fujimoto Y. A Web-Based Survey to Investigate the Extent of Awareness and Understanding for Biosimilar Among Japanese Physicians and Pharmacists. ISPOR 18th Annual European Congress; Milan2015.
23. O'Callaghan J, Bermingham M, Leonard M, Hallinan F, Morris JM, Moore U, et al. Assessing awareness and attitudes of healthcare professionals on the use of biosimilar medicines: A survey of physicians and pharmacists in Ireland. Regul Toxicol Pharmacol. 2017;88:252-61.
24. Goldsmith D, Dellanna F, Schiestl M, Krendyukov A, Combe C. Epoetin Biosimilars in the Treatment of Renal Anemia: What Have We Learned from a Decade of European Experience? Clin Drug Investig. 2018;38(6):481-90.
25. Weise M, Bielsky MC, De Smet K, Ehmann F, Ekman N, Giezen TJ, et al. Biosimilars: what clinicians should know. Blood. 2012;120(26):5111-7.
26. U.S. Food & Drug Administration (FDA). Considerations in Demonstrating Interchangeability With a Reference Product: Guidance for Industry (Draft). 2017.
27. Specialist Pharmacy Service. Adalimumab resources to use with patients 2018 [Available from: https://www.sps.nhs.uk/articles/adalimumab-resources-to-use-with-patients/.
28. American Pharmacists Association (APhA). Biosimilar Basics For Patients. 2018.
29. Cohen SB, Alonso-Ruiz A, Klimiuk PA, Lee EC, Peter N, Sonderegger I, et al. Similar efficacy, safety and immunogenicity of adalimumab biosimilar BI 695501 and Humira reference product in patients with moderately to severely active rheumatoid arthritis: results from the phase III randomised VOLTAIRE-RA equivalence study. Ann Rheum Dis. 2018;77(6):914-21.

30. Boehringer Ingelheim starts clinical study on interchangeability between its adalimumab biosimilar candidate and U.S.-formulated Humira [press release]. 2017.

31. DiGrande S. Are Rumors of AbbVie's Humira Price Cuts What They Seem? The Center for Biosimilars 2018.

32. NHS Improvement, NHS Clinical Commissioners, England N. Commissioning framework for biological medicines (including biosimilar medicines). 2017.

33. Greater Manchester Shared Services. Implementation and principles of a Greater Manchester biosimilar gainshare agreement. 2017.

34. Chelsea and Westminster Hospital. Request for information relating to gainshare agreements. 2015.

35. van der Zanden B. SWL Commissioning Principles for PbR Excluded Drugs / Devices 2017-19 Version 2 - 19 July 2017 in-year addendum. Appendix 2: South West London (SWL) Arrangements for Introduction of new Biosimilars (Rituximab, Etanercept 25mg and Adalimumab) – Gainshare and QIPP agreements. 2017.

36. Spitzenverband Bund der Krankenkassen (GKV-Spitzenverband), Kassenärztliche Bundesvereinigung. Framework requirements according to § 84 Abs. 7 SGB V. 2018.

37. 2017 Standard Formulary List [press release]. 2016.

38. Pharmacy Benefit Update [press release]. 2017.

39. Inserro A. FDA's Gottlieb Blames Rebates, Reimbursement Issues for Holding Back Biosimilar Market. The American Journal of Managed Care (AJMC). 2018.

40. European Medicines Agency. Neulasta : EPAR - Product Information. 2018.

41. Kirchisner E. GAZYVA®/ GAZYVARO™ - The Success Story of a Glycoengineered Antibody. CMC Strategy Forum; Japan2014.

42. DiGrande S. Amgen Gains Positive CHMP Opinion for Neulasta Onpro as Pegfilgrastim Biosimilar Competition Draws Closer. The Center for Biosimilars. 2018.

43. Mazzola J. Building a Premier Oncology Biotech. Jefferies Global Healthcare Conference2017.

44. Pharmaceutical Management Agency (PHARMAC). Decision to award sole supply to Remicade (infliximab) 2014.

45. AbbVie Announces HUMIRA® (adalimumab) Global Patent License with Momenta [press release]. 2018.

46. AbbVie Announces Global Resolution of HUMIRA® (adalimumab) Patent Disputes with Sandoz [press release]. 2018.

47. AbbVie Announces HUMIRA® (adalimumab) Patent License with Mylan [press release]. 2018.

48. AbbVie Announces Global Resolution of HUMIRA® (adalimumab) Patent Disputes with Amgen [press release]. 2017.

49. Enbrel® (etanercept) Patent Issued [press release]. 2011.

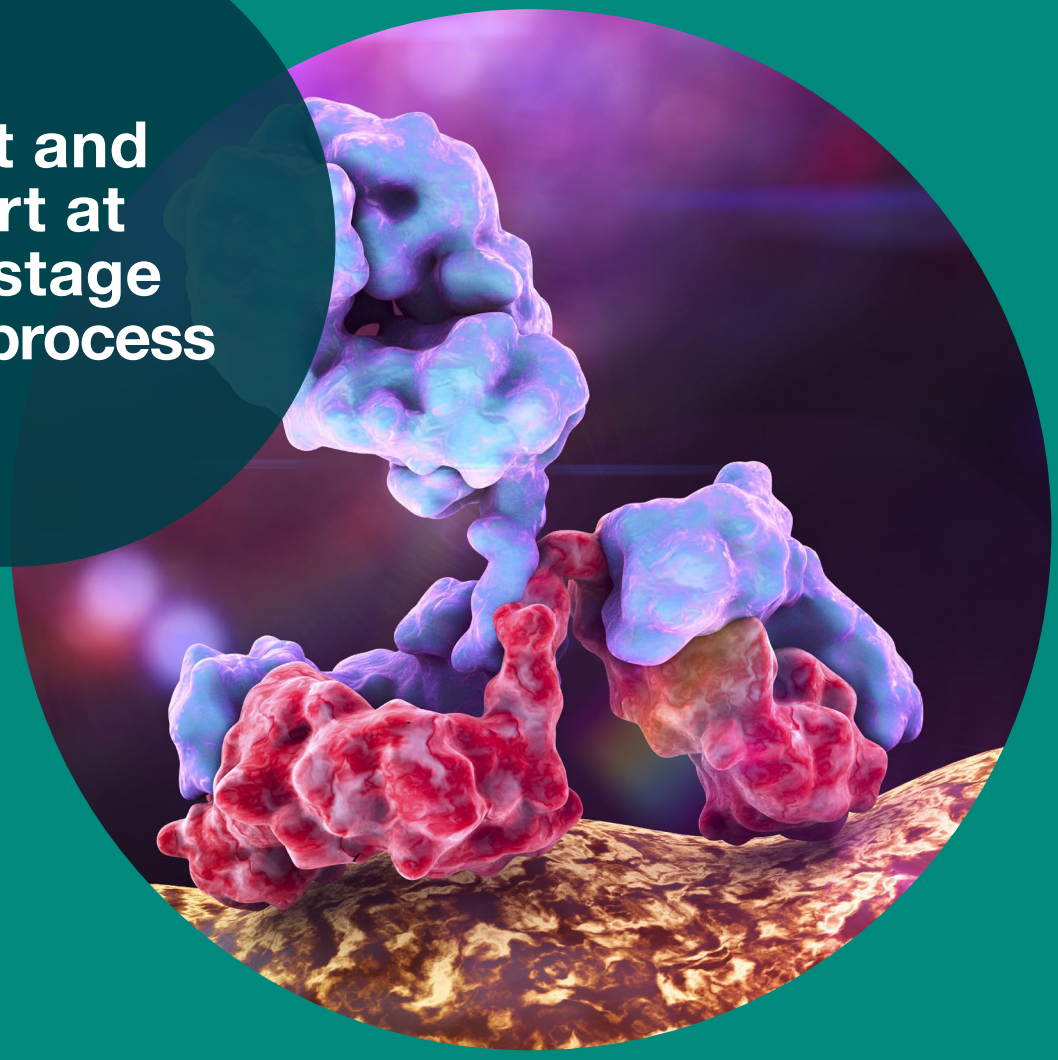
50. FDA Grants Tentative Approval for Lilly and Boehringer Ingelheim's Basaglar™ (insulin glargine injection) [press release]. 2014.

51. Station T. Sanofi patent deal lets Lilly roll out a Lantus biosim in U.S. next December. FiercePharma. 2015.

52. Statista. Projected annual global biologics revenue from 2016 to 2022 (in billion U.S. dollars) 2017 [Available from: https://www.statista.com/statistics/817593/revenue-forecast-for-global-biologics-market/

# Intregated Biosimilar Services

## Insight and support at every stage of the process



ICON provides a fully integrated approach to the development of biosimilar medicines. We offer strategic consulting to define the optimal development and commercial strategy coupled with the operational capabilities to conduct the requisite studies in an effective and timely manner. Specialist consultants will be with you at every stage of the process; from the selection of the target biologics, the characterisation of the structure, function of the molecule and process scale-up, phase I-III trial management leading to marketing authorisation, through to commercialisation.

Contact us today to discuss your next biosimilars program.

ICONplc.com/biosimilars

**ICON plc Corporate Headquarters**

South County Business Park
Leopardstown, Dublin 18
Ireland
T: (IRL) +353 1 291 2000
T: (US) +1 215 616 3000
F: +353 1 247 6260

ICONplc.com

## About ICON

ICON plc is a global provider of drug development and commercialisation solutions and services to pharmaceutical, biotechnology, medical device, and government and public health organisations. The company specialises in the strategic development, management and analysis of programs that support clinical development – from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 93 locations in 37 countries and has approximately 13,680 employees. Further information is available at ICONplc.com.