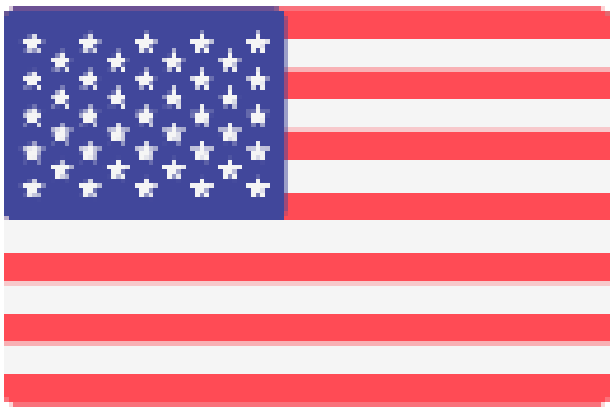
Unlocking the Potential of Biosimilars

A Roadmap for Biosimilar Policy Sustainability

Biosimilar Policy Landscape & Sustainability Assessment

United States of America



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Introduction

The adoption of biosimilars can offer significant benefits to stakeholders yet has not been a uniform and equal process across countries. Biosimilar uptake has shown large discrepancies across (and sometimes within) countries.[i, ii] For example, in 2020 the uptake of infliximab biosimilars was 89% in the UK versus 6% in Japan.[iii] Biosimilar utilization can also vary significantly within countries. For example, in a 2021 US study, practice setting (outpatient hospital department vs office practice, and for-profit vs not-for-profit) was found to be a key driver in biosimilar use.[iv] A country's policy environment likely affects the variation in biosimilar success. Assessing the current biosimilar policy landscape and the extent to which current policies support long-term sustainability for biosimilars is critical to understanding the drivers of success, inefficiency and risk areas of biosimilars in any given country.

Methodology

This study presents a global analysis of the biosimilar-specific policies across a wide range of countries. Country-specific policy landscapes are summarised according to an assessment framework of nine policy areas depicted in **Table 1**. Country-specific desk research was conducted to draft policy landscapes and were subsequently validated through 1:1 interviews with country experts.

Table 1 - Policy area assessment framework

	**Manufacturing and R&D**	Policies incentivising local/regional manufacturing or investing in biosimilar R&D
	**Regulatory Approval**	Policies ensuring streamlined or accelerated regulatory pathways at national or regional level
	**Health Technology Assessment**	Policies allowing for reduced or differentiated HTA requirements for biosimilars
	**Pricing & Reimbursement**	Policies mandating price reductions for biosimilars or originator products or affecting reimbursement
	**Contracting**	Policies governing purchasing, including national/sub-national tendering and procurement of biosimilars
	**Biosimilar Education & Understanding**	Policies or initiatives supporting biosimilars education
	**Prescribing**	Policies affecting physician uptake and prescribing
	**Dispensing**	Policies at pharmacy level affecting dispensing of biosimilars
	**Monitoring**	Policies ensuring monitoring of safety and efficacy of biosimilars

Source: CRA

During 1:1 interviews, a sustainability assessment of each policy area was conducted to provide a 'biosimilar sustainability rating'. Based on a literature review, a scorecard was developed and tested with biosimilar policy experts. The scorecard summarises the potential multi-stakeholder benefits of biosimilars using a 5-point 'star rating' scale. (See **Table 2**). In addition to country-specific documents, a cross-country summary and global analysis of the long-term sustainability of biosimilar policies is published in the White Paper 'Unlocking the Potential of Biosimilars: A Roadmap for Biosimilar Policy Sustainability'.[v]

Table 2 – 5-point 'star rating' scale

★★★★★	The policy area is considered to be sustainable **for all stakeholders**
★★★★☆	Some **minor areas** for improvement were identified to result in a fully sustainable environment, however no unsustainable policies impact the area
★★★☆☆	Some **major areas** for improvement were identified to result in a fully sustainable environment, however no unsustainable policies impact the area
★★☆☆☆	There are sustainable policies in place which are being negated by the **presence of unsustainable policies** in the same/different policy area
★☆☆☆☆	The (lack of) policies in place are considered to **actively contribute to an unsustainable policy environment** for the majority of stakeholders

Source: CRA

Assessment of US Biosimilar Policy Areas

	Policy Area	Summary	Star Rating	Comment
	**Manufacturing and R&D**	No specific biosimilars manufacturing policies but high numbers of patents can be registered for an originator product to form 'thickets', which significantly extend the originator's exclusivity period and prevents domestic production of biosimilars.	★★★☆☆	Biosimilars and originators are held to the same manufacturing standards. Manufacturing can only begin after originator LoE, incentivising ex-US manufacture and subsequent importation. 'Patent thickets' increase barriers to launch of biosimilars, delaying access for US patients.
	**Regulatory Approval**	The Biologics Price Competition and Innovation Act created a biosimilar regulatory pathway and streamlined requirements for biosimilar approvals, although demonstration of comparative clinical effectiveness is required in most cases. First interchangeable biosimilar earns one year of exclusivity.	★★★★☆	Streamlined requirements accelerate regulatory approval and reduce development cost. Exclusivity for the first interchangeable biosimilar provides an incentive to be first-to-market. Recent FDA inspection delays within the pharmaceutical industry may affect biosimilars.
	**Health Technology Assessment**	HTA is not required for biosimilars, similar to originator products.	★★★★★	Systematic HTA for biosimilars is not required given their implied cost-effectiveness. In the US market, HTA is not systematically applied for innovative products either.
	**Pricing & Reimbursement**	Medicare reimburses Part B biosimilars and originators with the same markup: 6% of the originator's average sales price (ASP). Exclusive originator contracting (e.g., minimum originator prescription quotas) is observed in commercial plans, and preferred reimbursement of biosimilars is occasionally observed. Some commercial plans offer patients co-payment incentives to use biosimilars.	Public: ★★★★☆ Commercial: ★★☆☆☆	Equivalent Part B reimbursement "markups' across biosimilars and their reference biologics eliminate any financial incentives to use the originator. However, Medicare lacks any incentive for biosimilar utilization. Biosimilar pricing is governed by competition and market dynamics, which have been shown to drive originator net discounting and result in cost-savings for payers. Proposals to allow the government to negotiate drug prices threaten the market for biosimilar manufacturers.

	**Contracting**	Contracting is currently done at the provider level, resulting in large variation in access to and penetration of biosimilars across the country. Contracting is a highly confidential process. Hospitals are likely to purchase a single biosimilar or the originator.	Public: ★★★★☆ Commercial: ★★★★☆	There is significant variation in contracting at the provider level. Access to biosimilars may be restricted by originator manufacturers' influence in defining drug formularies. Specifically, certain rebate agreements made with commercial plans can, in some cases, create barriers for biosimilars. So called 'rebate traps' may be anti-competitive. However, where cost-saving incentives are aligned, the current system allows for good biosimilar competition.
	**Biosimilar Education**	The Advancing Education on Biosimilars Act has driven the generation of educational materials, complementing the efforts of the Food and Drug Administration, the Federal Trade Commission and public workshops.	★★★★☆	Various tailored educational resources have been published to reach different stakeholders. Additional resources targeting physicians may drive greater uptake of biosimilars, as provider and patient understanding and acceptance of biosimilars varies across therapeutic areas.
	**Prescribing**	Medicare Part D plans can utilize step therapy for molecule-naïve patients with initiation on biosimilars. Some commercial plans also require biosimilar initiation, although rebate contracts still drive significant originator use.	Public: ★★★★☆ Commercial: ★★☆☆☆	Step-therapy requirements for biosimilars have been used to drive biosimilar uptake and capture savings.
	**Dispensing**	Interchangeability permits automatic substitution, but state law can limit this (e.g., with HCP notification requirements). Medicare policy ensures there are no direct financial disincentives for dispensing of biosimilars.	Public: ★★★★☆ Commercial: ★★★☆☆	Interchangeability ensures automatic substitution of a biosimilar if state law does not create a barrier.
	**Monitoring**	FDA has adopted a unique naming approach for all biosimilars requiring the addition of unique suffixes to the biologic's international non-proprietary name.	★★★★☆	Use of unique suffixes facilitates tracking and supports pharmacovigilance efforts. However, unique naming can fuel perceptions of inferiority relative to the originator.

Key Successes, Areas for Improvement & Risk Areas

Key Biosimilar Policy Successes
▲ Creation of a biosimilar regulatory pathway
▲ Availability of FDA's regulatory support for biosimilar manufacturers
▲ Broad stakeholder education initiatives
▲ Neutral Medicare reimbursement that avoids incentivising use of originator biologics
Key Biosimilar Policy Areas for Improvement
► Patent reform to accelerate access to biosimilars by reducing the impact of 'patent thickets' should be pursued and additional funding and reforms are needed at the US Patent Office.
► An increase in reimbursement for Medicare Part B biosimilars should be considered. Biosimilar reimbursement could be increased from ASP+6% to ASP+8% or a demonstration project through the Center for Medicare and Medicaid Innovation could be established.
► Some payers provide lower patient co-payments for biosimilars. However, stronger incentive policies to encourage physicians and patients to prescribe and utilize biosimilars is appropriate.
► Reduced requirement for comparative clinical trials for biosimilars
► Legislation to facilitate automatic substitution is necessary in some states.
Key Biosimilar Policy Risks
▼ Excessive use of 'rebate traps' and 'patent thickets' by originator manufacturers, can limit insurer use of biosimilars and the availability of biosimilars generally
▼ A recent Drug Competition Executive Order has proposed equalising the reimbursement (J-codes) for biosimilars and originators which would be detrimental to biosimilar pricing, triggering an unsustainable 'race to the bottom'
▼ Legislative proposals to introduce Medicare price negotiations, limit price increases to inflation, and other changes to Medicare may diminish the sustainability of the biosimilar market
Key Biosimilar Policy Priorities to Achieve Long-Term Sustainability
1. Maintenance of differentiated biosimilar reimbursement codes in Medicare to ensure that unsustainable price reductions do not occur
2. Addressing anti-competitive use of 'rebate traps' and 'patent thickets' in order to support sustainable biosimilar competition
3. Introduction of incentives to drive biosimilar prescription (e.g., ASP+8%)
4. Reduction of patient out-of-pocket costs for biosimilar utilization

5. Maintenance of a robust and competitive marketplace to provide sustainability for manufacturers' biosimilars development projections
6. Exclusion of biosimilars from any federal legislation requiring drug price negotiations
7. Passage of the Biosimilar User Fee Act III to streamline FDA review and approval and address inspection backlogs

Policy Landscape Assessment

Manufacturing and R&D

There are no specific manufacturing policies for biosimilars. However, given that manufacturing in the US cannot practically begin until after patent disputes are resolved, patent thickets by originator manufacturers can limit the domestic manufacture of biosimilars. A recent analysis of 21 patent infringement lawsuits found that only 6% of patents covered the key ingredients in biologic medicines.[vi] The remaining patents cover aspects considered to be 'secondary uses', including the manufacturing process, methods of using a medicine and alternative formulations. The risk of infringing an originator's patents can act as a disincentive for US biosimilar manufacturers from developing and launching biosimilar products, restricting long-term access.[vii]

One recent regulatory reform to consider is a rule to increase the domestic content threshold for qualified 'Made in America' products from 55 percent to 75 percent by 2029. While this policy is not narrowly related to biosimilars (or even pharmaceuticals in general) it may have the unintended consequence of discouraging partial US manufacturing of biosimilars given the higher content requirement for qualifying.

Regulatory Approval

Biosimilar pathway and streamlining evidence requirements

In March 2010, the Biologics Price Competition and Innovation Act created an accelerated pathway for companies to bring biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed reference product.[viii] Overall, this reduces the burden on the biosimilar manufacturer, although there are still significant evidence generation requirements.

Currently, the FDA requires comparative clinical efficacy studies for all biosimilar development programs.[ix] However, in a few cases, the FDA has waived this requirement (e.g., Retacrit (erythropoietin), Nivestim (filgrastim), and Udenyca (pegfilgrastim)).[x] FDA officials have acknowledged that the agency should align more closely with the European Medicines Agency in relaxing their requirements for comparative clinical efficacy studies.[xi] In 2018, the FDA created the Biosimilars Action Plan, which noted that the agency is 'modernizing regulatory policies to accommodate new scientific tools that can better enable comparison between biosimilars and reference products that may reduce the need for clinical studies.'.[xii]

Market exclusivity for interchangeable biosimilars

Under Section 351(k)(6) of the Public Health Service Act, the FDA will not grant interchangeability status for any second biosimilar for one year after the first interchangeable biosimilar enters the market. This provides an incentive for manufacturers to launch the first interchangeable biosimilar of a given branded originator.[xiii] Few biosimilar manufacturers have sought an interchangeable designation. However, there is some concern that the existence of an interchangeable designation poses a risk that a 'two-tier' system is created, leading to misconceptions about biosimilars that are not interchangeable. Furthermore, the resource requirements for the current review process for interchangeability have introduced an additional barrier (as seen for infused products). However,

Regulatory support and limitations

The FDA has created the biosimilar biological product development (BPD) program to facilitate the rapid development of biosimilars. Prospective manufacturers of biosimilar products pay BPD fees to enrol in the program and receive detailed, product-specific advice, supporting them in meeting the FDA's regulatory and manufacturing requirements.[xiv]

During the pandemic, the FDA began postponing manufacturing site inspections, resulting in a significant backlog and residual delays. These delays are experienced domestically and internationally and may negatively impact the quality or volume of biosimilars sold in the US.[xv]

Health Technology Assessment

Not applicable in the U.S. as there is no formal (pre-launch) HTA system established.

Pricing & Reimbursement

Biosimilar reimbursement

Since 2018, each biosimilar is given its own Healthcare Common Procedure Coding System (HCPCS) code and its average sales price (ASP) is not combined with other biosimilars of the same reference product. Medicare reimburses Part B drugs at their ASP plus 6% of the reference product ASP, ensuring that there are equivalent reimbursement incentives for biosimilar and originator use.

Some commercial plans have implemented preferred reimbursement for certain biosimilars,[xvi] along with utilization management programs to increase biosimilar use.

A recent Drug Competition Executive Order (September 2021) has proposed equalising the reimbursement (J-codes) for biosimilars and originators. Although this proposal has not been implemented yet, this could be detrimental to biosimilar pricing, triggering unsustainable pricing reductions with potential for a 'race to the bottom'.[xvii]

Proposals to negotiate drug prices

Many lawmakers have made proposals to allow the government to negotiate drug prices as a way to control healthcare costs.

Most recently, H.R. 5376, the Build Back Better Act (BBB), passed the House of Representatives and is under consideration in the Senate., H.R. 5376 would allow the government to negotiate drug prices for a set number of high-cost drugs in Medicare Part B and Part D and would impose a stiff excise tax on manufacturers that did not participate in the negotiation. By effectively forcing price reductions on biologic drugs, this policy would likely have a large impact on biosimilars by interfering in the market in which biosimilars aim to create competitive price pressures. This could lead to a chilling effect, fewer biosimilars being developed.

Originator discounts at biosimilar launch

Mandated discounts are not required, although originator (net) discounts do occur with increasing biosimilar competition across the Medicare and private settings. Generally, discounts of ~30% are initially expected, although greater discounts do occur and are expected to be provided more frequently in future.[xviii]

Reduced patient co-payment

In Medicare Part B, patients are responsible for 20% of the cost of the drug. Hence, they pay less when treated with a less costly biosimilar alternative, although a relatively low number of patients are actually responsible for paying this 20% co-payment.[xix] Some commercial plans in the U.S. require lower out-of-pocket payments for biosimilars, providing an incentive for patient use.[xx]

Contracting

Scope of contracts

Provision of biosimilars or originators is often defined by contracting at the provider-level, hence there is significant variation among providers. For example, bevacizumab biosimilar usage has been shown to range from 0–100%.[xxi]

Given that Medicare Part B (through which most biosimilars are covered) does not permit use of a formulary, biosimilar provision is defined by the treating centre and the procurement approach they take.[xxii]

Alignment of cost-saving incentives across stakeholders is critical to support sustainable competition within the market which provides the opportunity for competitive manufacturer strategies. One such policy is reflected in equivalent Part B reimbursement “markups’ that are applied across biosimilars and their reference, eliminating any financial incentives to use the originator.

Exclusion contracts

Some commercial plans require patients to try the originator first, before gaining access to the biosimilar, as defined by the plan’s formulary preferences.[xxiii, xxiv] Plans derive benefit from this through confidential rebate agreements with the originator’s manufacturers. These rebate agreements are often dependent on the originator’s (large) market share being maintained, providing an obstacle for future biosimilar entry.[xxv] Furthermore, manufacturers may provide these rebates on the condition that market shares are maintained across their portfolio of products. This type of anti-competitive agreement is referred to as a ‘rebate trap’.[xxvi]

Biosimilar Education & Understanding

Health care professional (HCP) educational programs

The FDA has created educational materials for HCPs that cover a variety of biosimilars topics, including their benefits, how they are developed and approved, and the concept of interchangeability. These materials include videos, fact sheets and infographics.[xxvii] The FDA and the Federal Trade Commission have hosted joint public workshops (e.g., in 2020) to discuss reasons for limited biosimilar uptake in the

U.S. Biosimilar manufacturers were also invited to discuss current misinformation and address disparagement of biosimilars by originator companies.[xxviii]

The U.S. Congress has recognised the importance of unbiased information sources in gaining stakeholder trust in biosimilars. In April 2021, Congress enacted legislation (the Advancing Education on Biosimilars Act) that directs the Secretary of the Department of Health and Human Services (HHS) to create a website that explains the standards FDA uses to review biologics and biosimilars, to help address clinician and patient misperceptions about biosimilars.[xxix] However, there are still HCPs with limited understanding about biosimilars and their value to patients, which translates to variable acceptance amongst HCPs across therapy areas.

Private insurers are also involved in HCP education efforts, fostering increased biosimilar usage. Kaiser Permanente successfully switched a large proportion of its patients from originator biologics to biosimilars following education campaigns. Leveraging their own real-world data on biosimilar performance, Kaiser worked with their 'frontline' providers and HCPs to highlight the benefit of patients switching to biosimilars.[xxx]

Patient educational programs

Additional educational materials for patients are disseminated by the FDA, providing detailed information in multiple languages to address frequently asked questions. These include videos, fact sheets and infographics that discuss the basics and benefits of biosimilars and their development and approval process.[xxxi] Furthermore, the FDA has developed a 'stakeholder toolkit' that helps HCPs educate patients themselves.[xxxii]

Prescribing

In 2019, the Centers for Medicare & Medicaid Services allowed Medicare Part B plans to introduce step-therapy requirements for treatment-naïve patients. This policy includes use of biosimilars, including Retacrit (epoetin alfa-epbx), Inflectra (infliximab-dyyb) and Renflexis (infliximab-abda). Consequently, patients are initially treated with the 'preferred therapy' (generally a biosimilar) and only once they satisfy various criteria (e.g., history of biosimilar use/intolerance) are they able to use the 'non-preferred therapy' (e.g., originator).[xxxiii] Reflecting this, some commercial plans also require biosimilar initiation, although rebate contracts still drive significant originator use within the private sector.

Dispensing

Automatic substitution

Biosimilars cannot be used as a substitute for their reference products without a prescriber's intervention unless the FDA designates the biosimilar as "interchangeable".[xxxiv] To achieve interchangeability, the FDA requires a manufacturer to provide data to evaluate the risk, in terms of safety and efficacy, of alternating or switching between the products, if the product is administered to a patient more than once. These

precautions were based on a concern regarding biosimilar immunogenicity, but notably, adverse immunogenic events have not materialised from switching.[xxxv]

Further limitations on substitution/interchangeability are defined at the state level. As of 2019, 45 states have laws promoting automatic substitution/interchangeability.[xxxvi] In some cases, there is a requirement for the patient's physician to be notified following substitution (e.g., as seen in Maine).[xxxvii]

Biosimilar penetration at pharmacies is influenced by insurance type and competitive actions by originator manufacturers. Pharmacy benefit managers (PBMs) are the key stakeholder in the negotiation of formularies and/or rebates and may prefer either biosimilar or originators based on the financial incentives provided to them.

In some states, e.g., Maryland (through HB 664), pharmacists are required to inform patients when there is a less costly therapeutically equivalent drug or interchangeable biologic.[xxxviii]

Monitoring

Pharmacovigilance measures

In order to support potential monitoring efforts, the FDA has adopted a unique naming approach for all biosimilars in the U.S., which involves the addition of unique four-letter suffixes at the end of the biologic's international non-proprietary name (INN).[xxxix] For example, the INN of Inflectra is 'infliximab-dyyb', which is a biosimilar of Remicade (infliximab), whilst Renflexis (also an infliximab biosimilar) is 'infliximab-abda'. The application of this naming system permits the FDA to monitor biosimilars in post-market surveillance systems. However, assignment of different INNs to biosimilars does influence their perception, potentially fuelling incorrect impressions of their inferiority.

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