Australia Biosimilars Progress Report

In the quest to unlock the full potential of biosimilars, the information below represents the journey of Australia towards biosimilar sustainability. For more information see the full report at www.biosimilarsroadmap.com

Policy Assessment Summary ➔ And implications:

Manufacturing and R&D

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No policies specific to biosimilar manufacturing have been identified. Otherwise, biosimilars are subject to the same quality and safety standards as other biologics. ➔ Biosimilars are held to the same manufacturing standards as originator products therefore quality is maintained. However, manufacturing can only begin after originator loss of exclusivity (LoE), which can result in slower access to the market and delay in the benefits realised by biosimilar entry.

Regulatory Approval

★★★★☆

Streamlined clinical evidence requirements (including the option to reference data from comparisons versus products other than the originator) as well as the potential for indication extrapolation. ➔ Evidence requirements can be streamlined without affecting safety or quality, and product development partnership (PDPs) offer an accelerated pathway for biosimilars' approval. However, more transparent and clear regulations regarding the use of the individual pathway are required and the need for clinical comparative assessment studies could be reduced to further streamline regulatory approval.

Health Technology Assessment

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Streamlined pharmacoeconomic requirements reduces barriers to assessment and reduce application fees. ➔ Health technology assessment (HTA) is required for biosimilars which ensures that uptake drivers are awarded consistently to biosimilar products (e.g. a-flagging status). The streamlining of evidence requirements simplifies the process, although the assessment process is not formally accelerated.

Pricing & Reimbursement

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Mandated originator list discounts (25-60%) at biosimilar launch with reference pricing and additional progressive originator price discounts (every 5 years) both degrade biosimilar price benchmarks. ➔ Reference pricing homogenises pricing across products based on the cheapest product not allowing for differentiation. Mandatory discounts erode price benchmarks, disincentivising ongoing innovation and future competition.

Contracting

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Contracting varies across markets (hospital vs. community pharmacies); single-winner contracts used in some hospital pharmacies. ➔ Single-winner tenders restrict competition within the market, increase the risk of supply shortages and exclude smaller manufacturers. However, since procurement varies across stakeholder groups, this stimulates plurality meaning the negative impact of this is limited.

Biosimilar Education & Understanding

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Biosimilar Awareness Initiative provides funding for HCP/patient education programmes. ➔ National educational efforts targeted at healthcare professionals (HCPs) and pharmacists have likely contributed to broader uptake of biosimilar products, although significant misconceptions are still present in the market, especially among prescribers and patients.

Prescribing

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Biosimilar switching and initiation are recommended and securing authorisation for biosimilar prescriptions are streamlined. International non-proprietary name (INN) must be used in prescriptions, but the brand can be specified, giving control of dispensing to physicians. ➔ Biosimilar switching is recommended, alongside patient involvement, but not mandated thus allowing physicians to have choice and flexibility in prescribing. Prescription of biosimilars over originators is encouraged by streamlined PBS authorisation however, there are no financial incentives to support uptake.

Dispensing

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'A-flagging' enables automatic substitution of some biologics and there can be financial incentives for dispensing cheaper biologics. ➔ Physicians can specify the brand during prescribing, limiting substitution. No differential in patient co-pay for biosimilar versus the originator. However, poor physician education can lead to inappropriate restriction of substitution and diminished positive impacts of substitution policies.

Monitoring

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No specific Australian policies have been identified differentiating biosimilar monitoring from other pharmacovigilance efforts. Regulatory approval can be contingent on biosimilars having risk management plans if they are requested, although they rarely differ from those of the originator. Surety of supply is driven by limits on dispensing >1 month of a prescription, increased stocking requirements for manufacturers and wholesalers.

➔ Risk management plans support monitoring efforts, although batch-level traceability it limited, and supply guarantees can be opaque. The option to specify the brand in prescriptions diminishes the potential negative impact of INN prescribing. Measures have been implemented to ensure the surety of supply, mitigating against shortage risks.

Areas of Success, Improvement and Recommendations:

Key Biosimilar Policy Successes

Various public health education initiatives with multiple different outputs.

Recommendations for biosimilar initiation and switching, alongside streamlined authorisation requirements.

The latest strategic agreements signed (expected to enter into force in 2022) between the GBMA, Medicines Australia and the Government has been updated to highlight the potential to implement additional uptake drivers for biosimilars in future.

Key Biosimilar Policy Risks

There is a lack of biosimilar awareness and education amongst policymakers and patients; in some cases, biosimilars are perceived and treated in a similar manner to generics, leading to potentially unsustainable practices.

Statutory price reduction mechanisms (clause 4 of the GBMA's strategic agreement) which do not differentiate between biosimilars and generics, introducing aggressive launch discounts for the first biosimilar, unsustainably eroding pricing.

Stockholding requirements (clause 3.6 of the GBMA's strategic agreement) dictate that from 2023, manufacturers will be required to hold 4-6 months of stock, which is significantly more challenging for biosimilars (relative to generics) given their higher prices.

Key Biosimilar Policy Areas for Improvement

Although HTA for biosimilars is accelerated (and cheaper) given that economic evaluation is not required; biosimilars still must undergo a formal HTA process to launch in Australia after Therapeutic Goods Administration (TGA) approval. Allocation of uptake drivers (e.g. 'A-flagging') is also contingent on the HTA process. There could be potential to streamline regulatory and HTA processes and provide access to biosimilars more efficiently.

Lack of differentiation in co-payments for biosimilars and originator biologics; introduction of lower co-payments for biosimilars would provide a financial incentive for patient use Therapeutic reference pricing where the benchmark is set by the lowest cost brand.

Financial incentives for dispensing pharmacists could be aligned with physician incentives and formalised to encourage increased biosimilar uptake.

Key Biosimilar Policy Priorities to Achieve Long-Term Sustainability in Australia

Align incentives across all key stakeholders, including physicians, pharmacists and patients.

Decrease the co-payment for patients who choose a biosimilar, so as to incentivise patients directly.

Increase multi-disciplinary decision-making regarding dispensation of biosimilars.

Optimise existing pricing and reimbursement policy to mitigate impact of erosion driven by mandatory discounts.

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