Biosimilars: A global roadmap for policy sustainability

Executive Summary

Report Methodology:

A literature review was undertaken to develop a 'sustainability scorecard' of 10 elements that characterise a sustainable environment for biosimilars. Country policy landscape assessments were then conducted and followed by two international advisory boards to inform the development of actionable policy recommendations.

Geographic Scope:

Overarching Learnings

- The introduction of biosimilar policy should be anchored in supporting the goal of sustainability in the short and medium term, ensuring cross-stakeholder perspectives are captured.
- As a country's biosimilar landscape matures over time and stakeholder experience increases, there is a need to periodically evaluate and update policies to ensure sustainability is maintained.
- Policies are less effective when implemented in a piecemeal fashion, hence implementation should consider the existing policy environment and where synergies can be leveraged across policy areas.
- Similarly, policies should adapt to reflect the changing types of biologics losing exclusivity.
- Cultivation of a sustainable global biosimilar landscape requires sharing of learning and best practices across markets, to support accelerated development of countries with less mature biosimilar landscapes.

Key Questions and Findings:

Can we define an 'ideal' biosimilar policy toolkit that will ensure long term sustainability that is applicable across different market circumstances, across different types of biosimilars?

- Biosimilar policy environments cannot be considered in isolation, and therefore the 'ideal biosimilar policies' vary across countries depending on:
  - The country's level of experience with current biosimilars
  - The country's existing pharmaceutical policies, including pricing and reimbursement processes, contracting approaches
  - The type of product under consideration
- Across the nine areas, we find that policies which do not differentiate between biosimilars and generics are generally more likely to be unsustainable. There is a need for a specific set of biosimilar policies.
- Although the sustainability provided by a specific policy can differ between countries, and there exist few policies that are universally sustainable, we can define a set of 'ideal policy sustainability principles, or elements, to govern the development of biosimilar policy.
- Biosimilar policy should be developed over time:
  - Initially, biosimilar policies should focus on ensuring the safety and quality of biosimilars, safeguarding healthy levels of supply and delivering a level of cost savings.
  - As biosimilars become more established, policies should seek to optimize uptake and combat any misconceptions regarding biosimilars.
  - Ultimately, countries should aim for biosimilar policies that encourage competition, broadening treatment options and ensuring a sustainably functioning biosimilar market.

To what extent does existing biosimilar policy across a global selection of countries promote a long-term sustainable environment?

- Generally, current approaches to biosimilar manufacturing and R&D incentives and exemptions to the application of health technology assessment (HTA) to biosimilars are sustainable.
- Across countries there is room for improvement with regards to biosimilar contracting approaches and with ensuring biosimilar education and understanding.
- European markets, which tend to have more experience with biosimilar products and more developed policy, generally have higher long-term sustainability ratings. Key successes include:
  - High levels of uptake driven by acceptance and trust from physicians and patients
  - Efficient access due to streamlined manufacturing, regulatory and HTA approaches
- Conversely, markets with more limited experience with biosimilars (e.g., Saudi Arabia, Japan) have more limited biosimilar policy, resulting in higher risks to long-term sustainability of the market. Key challenges include:
  - No differentiation between biosimilar and generic policies
  - Decreased traceability in pharmacovigilance systems
  - High levels of mistrust in biosimilars based on miseducation or limited transparency in regulatory processes within the market
- Given the differences in US markets, it is unsurprising there are some different challenges and policy solutions to promote biosimilar entry (e.g., the first biosimilar product deemed interchangeable is entitled to exclusive interchangeability for one year).

Can we provide countries with tangible and actionable recommendations for meaningful improvements to the biosimilar sector that consider their specific policy market archetype and different types of biosimilars?

Biosimilar policy recommendations across the nine key policy areas include:

Manufacturing and R&D

Biosimilar manufacturing policies should ensure the highest standard of quality and allow for prompt submission to regulatory authorities upon originator loss of exclusivity (LoE) while respecting intellectual property.

Regulatory Approval

Biosimilar regulatory processes should seek efficiencies to accelerate access timelines while maintaining robust processes that will ensure safety of biosimilars. Regulators should consider the biosimilar type, number of biosimilars already available and the submitted indication to determine required evidence for submission.

Health Technology Assessment

Conventional HTAs should be unnecessary given the similarity of biosimilars. However, it might be warranted in cases where: the originator biologic is not reimbursed, biosimilars offer a different route of administration than the originator, or biosimilars are considered to provide added-value services compared to the originator. If used, HTA should not delay access and should provide tangible benefits to the assessed product, such as ability to differentiate within tenders.

Pricing & Reimbursement

Policies should distinguish between biosimilars and small molecule generics. Depending on the policy landscape, either mandatory price controls or dynamic price controls (reliant on market competition) can be considered sustainable provided there are safeguards to ensure competition and sustainable price levels.

Contracting

Awarding of contracts (whether through direct negotiation or tendering) should include input from multiple stakeholders and allow for factors beyond price (e.g., quality and value) to contribute to decision-making. Policies should also facilitate competition between multiple suppliers for a country to minimise risk of supply shortages.

Biosimilar Education & Understanding

Biosimilar education is important for all key stakeholders (e.g., governments, budget holders, healthcare professionals [HCPs], pharmacists and patients) to ensure a holistic understanding of biosimilar value. The source of educational campaigns is critical to ensure trust in messaging, and peer-to-peer education is often an optimal educational method.

Prescribing

Use of the ‘best value’ biologic(s) should be encouraged, considering price, data on switching, prior treatment history, value added services, quality and supply. There is a role for multidisciplinary input to decision making but with physicians ultimately responsible for ensuring the most appropriate biologic is prescribed for each individual patient.

Dispensing

There is a debate regarding the role of substitution in many countries. Any decision should be based on multidisciplinary input to ensure the best outcomes for patients and best value for the healthcare system. It should be recognised that no ‘one size fits all’ approach will work while there variation in available switching data, setting of care (inpatient vs. outpatient) and individual therapies.

Monitoring

Biosimilars should be subject to the same pharmacovigilance standards as all biologics. Any policies implemented that risk decreasing biosimilar traceability should be mitigated by additional pharmacovigilance measures. Furthermore, transparency into biosimilar supply and demand can ensure healthy levels of supply are maintained.

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