Strengthening Global Access to Medicines

Medicines for Europe Recommendations for a Free and Fair Trade Policy

June 2025

Executive Summary

Medicines for Europe, the European Association of generic, biosimilar and value added-medicines manufacturers, proposes five key recommendations to strengthen global access to medicines, improve patient access and enhance the competitiveness of the off-patent pharmaceutical sector.

Also based on the findings of the 2024 Medicines for Europe report on market access barriers faced in 11 key third-country markets, the recommendations aim to remove trade barriers, promote regulatory convergence, and foster partnerships that ensure a steady, affordable supply of high-quality medicines globally by:

1. **Removing Tariffs, Non-Tariff Barriers and Export Restrictions while Fostering Security of Global Supply**: Advocate for the removal of tariffs and other trade barriers as well as export restrictions to ensure the free flow of medicines and their components, safeguarding global supply chains and protecting patient access.

2. **Recognising the Strategic Importance of Sustainable Pharmaceutical Manufacturing**: Promote the sustainability of off-patent pharmaceutical manufacturing, including securing access to funds for green and digital transitions and ensuring a diverse supply chain.

3. **Working towards Fair and Reciprocal Market Access**: Foster dialogue with international partners, namely via free trade agreements, to ensure fair market access, promoting competition and enhancing access to generic, value-added, and biosimilar medicines.

4. **Ensuring Balanced Intellectual Property (IP) Frameworks**: Advocate for balanced IP rules in Free Trade Agreements (FTAs) that ensure timely access to generic and biosimilar medicines by carefully assessing the need to propose any additional exclusivity measures.

5. **Improving Regulatory Convergence**: Prioritise regulatory convergence by harmonising regulatory standards and optimising approval processes. This includes exploring mutual recognition agreements for Good Manufacturing Practices (GMP) and developing strategies for the global development of generic and biosimilar medicines.

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Background

Medicines for Europe, the European Association of generic, biosimilar and value added-medicines manufacturers, proposes 5 recommendations to consider for a free and fair trade policy, improved patient access to medicines, and increased competitiveness of the off-patent pharmaceutical sector in the region. Generic, biosimilar and value-added medicines play an essential role in improving patient access to high-quality, safe, and effective treatments globally. We firmly believe that we can be stronger by working together through partnership towards the security of global supply serving the needs of people and patients.

In Europe, generic medicines represent 70% of all dispensed medicines while in countries, such as the United States and India, they account for 90% and more[1].

Biosimilar medicines have enabled Europe to save €50 billion between 2006 and 2023, including €10 billion in 2023 alone and they have the potential to dramatically increase access for patients. These products offer a significant opportunity for both high-income and lower-income countries to dramatically expand access to vital biological therapies for patients.

The generic, biosimilar medicines sector, also actively engaged in continuous innovation through value-added medicines, represents a pillar of industrial excellence within the European Union. This is demonstrated by its workforce of 190,000 employees across over 400 manufacturing sites. Value added medicines offer an affordable model for drug innovation covering repurposing, reformulation and combinations. They offer solutions to improve drug adherence for better chronic disease outcomes (i.e. for cardiovascular health), solutions for drug resistant infections, the use of medicines for preventive or prophylactic treatment and to enable cost-effective development for orphan diseases.

The trade of generic, biosimilar, and value-added medicines is essential, not only for global access to affordable and quality assured treatments to meet the needs of people and patients, but also for the competitiveness and growth of EU-based pharmaceutical companies.

In 2024, Medicines for Europe commissioned a report [2] to identify the main barriers to market entry faced by EU-based generic and biosimilar pharmaceutical companies operating in 11 key third-country markets (Australia, Brazil, China, India, Indonesia, Japan, Kazakhstan, Republic of Korea, South Africa, Türkiye, U.S.).

Based on the findings of the report, Medicines for Europe has developed the following recommendations for consideration in the European Union's trade policy:

1. Remove tariffs, non-tariff barriers and export restrictions while fostering security of global supply
2. Recognise the strategic importance of sustainable pharmaceutical manufacturing
3. Work towards fair and reciprocal market access
4. Ensure balanced intellectual property (IP) frameworks
5. Improve regulatory convergence

[1] IGBA (2024), Market Penetration of Generic Medicines

[2] Vulcan Consulting (2024), Market Access Barriers – An overview of key barriers to generic and biosimilar market entry in select EU trading partners

1. Removing Tariffs, Non-Tariff Barriers and Export Restrictions while Fostering Security of Global Supply

A key priority for Medicines for Europe is to maintain patient access to medicines by advocating for the removal of trade barriers, including tariffs and non-tariff barriers, that hinder the efficient supply of medicines across regional and international markets. Robust and well-functioning global supply chains are fundamental to ensure the consistent availability of medicines to people and patients. Any disruption to existing global supply chains, such as the imposition of tariffs or other access barriers, could negatively impact patient access to essential treatments, exacerbate existing and potential shortages and threaten the sustainability of the generic and biosimilar medicines industry.

It is therefore proposed that the European Union consider intensifying efforts to systematically reduce and eliminate tariffs on all finished medicines, active pharmaceutical ingredients, raw materials, chemicals and equipment used in medicine manufacturing.

Similarly, Europe should continue to advocate against export restrictions and other non-tariff barriers that can undermine access to medicines by blocking the trade of medicines and their components, especially during health crises.
The Covid-19 pandemic confirmed the importance of global solidarity, security of global supply and increased coordination between international partners. To this effect, the EU should include chapters on the security of global medicine supply in Free Trade Agreements (FTAs) and other partnership agreements with third countries.

Initiatives such as the Global Gateway represent an opportunity to improve global access to medicines, strengthen health systems in third countries and create new investment opportunities for EU-based companies.

Recommendations:

- **Remove tariffs, non-tariff barriers and export restrictions** affecting pharmaceuticals and their components to ensure the free flow of these products to safeguard medicines supply chains and protect access for people and patients.
- **Include chapters on security of global medicine supply** in FTAs and partnerships.
- **Leverage initiatives such as the Global Gateway** to support third countries in strengthening their healthcare systems and foster deeper supply chain partnerships with EU-based manufacturers of APIs and medicines.

2. Recognising the Strategic Importance of Sustainable Pharmaceutical Manufacturing

Pharmaceutical manufacturing is a cornerstone for sustainable access to medicines, health system strengthening and resilience, public health preparedness and economic competitiveness. The manufacture of generic, biosimilar and value-added medicines is essential to ensure the reliable supply of medicines that are crucial for patient care and economic vitality. Their production depends on complex, globally integrated supply chains, involving the sourcing of active pharmaceutical ingredients (APIs), excipients, and other essential components as well as the manufacturing of finished products across multiple countries. Disruptions to this network can significantly impact the availability and affordability of critical and essential medicines.

In an increasingly competitive and challenging global landscape, the European Union must actively promote a robust, sustainable and dynamic pharmaceutical manufacturing ecosystem. The findings of our report clearly confirm that several major trading partners have been moving in this direction.

Initiatives launched in recent years include for instance:

- In the U.S.,
  - The U.S. National Biotechnology and Biomanufacturing initiative[3] to grow domestic biomanufacturing and strengthen the U.S. supply chain producing domestic fuels, chemicals and materials
  - The Executive Order on "Regulatory Relief to Promote Domestic Production of Critical Medicines" [4]

- In India,
  - The Production Linked Incentive schemes [5] , supporting production of several pharmaceutical goods including biopharmaceuticals, complex generics, repurposed drugs, APIs, key starting materials, drug intermediates
  - The Vision Pharma 2047 [6] aiming to make India the global leader in manufacturing of affordable, innovative and quality pharmaceuticals and medical devices.

Recommendations:

- Adopt an ambitious **Critical Medicines Act** to ensure the sustainability of the off-patent industry. This should include ensuring access to funds for the green and digital transition in manufacturing, integrating supply security and diversity into market regulation and fostering stronger international cooperation on security of supply.
- Integrate the biosimilar medicines industrial sector in the **Biotech Act**.
- Ensure that **horizontal measures**, including environmental legislation, are balanced and pursue their objectives without inadvertently undermining the objectives of the Critical Medicines and Biotech Acts.

[3] FACT SHEET: President Biden to Launch a National Biotechnology and Biomanufacturing Initiative | The White House
[4] Federal Register: Regulatory Relief to Promote Domestic Production of Critical Medicines
[5] https://pharmaceuticals.gov.in/schemes
[6] Press Release: Press Information Bureau

3. Working towards Fair and Reciprocal Market Access

Access to third-country markets offers significant growth opportunities for EU-based pharmaceutical companies, fosters competition and enhances patient access to medicines. However, competing with local players often remains challenging in different country contexts.
Manufacturers often encounter discriminatory measures in local pricing and reimbursement or procurement systems, putting them at a disadvantage compared to domestic suppliers.

In discussion with international partners, Europe should continue to advocate for frameworks that are transparent, fair and reciprocal, ensuring equitable opportunities for market access.

Recommendation:

- Foster dialogue with international partners, including through FTAs and other bilateral partnerships, to **maintain reciprocal access** to markets to ensure competition and boost access to generic, value added and biosimilar medicines.

4. Ensuring Balanced Intellectual Property (IP) Frameworks

Balanced intellectual property (IP) rules are essential to ensure both innovation and broad and sustainable patient access to medicines.

The European Union should advocate for IP provisions in FTAs that encourage innovation, while ensuring timely competition and patient access to generic and biosimilar medicines.

While compliance with the standards established in the TRIPS Agreement is important, additional measures that prolong exclusivities, such as patent term extensions, or introducing new exclusivities, such as regulatory data and market protection, should not be automatically considered in the EU's proposals for trade agreements. Such measures should instead be carefully assessed case-by-case, considering the economic and public health conditions of the negotiating partner, as well as the potential for exporting EU-produced generic and biosimilar medicines to that country.

Moreover, the EU should not support the inclusion of patent linkage systems, declared illegal in Europe and considerably delaying market entry of generic and biosimilar medicines in several jurisdictions by blocking the ability to prepare a regulatory submission while the patent is active.

Recommendation:

- Ensure intellectual property provisions in FTAs balance incentives for innovation with **timely patient access to generic and biosimilar medicine**s, carefully assessing the need for any additional exclusivity measures.

5. Improving Regulatory Convergence

The European Union should prioritise the importance of moving towards regulatory convergence throughout policymaking engagements, including trade negotiations, by encouraging the harmonisation of regulatory standards, promoting regulatory reliance, and reviewing regulatory systems for optimised approval processes to accelerate access to medicines, eliminate unnecessary duplications and improve efficiency and predictability.

There is significant scope for improving regulatory alignment and reliance, even with established regulatory partners. For instance, expanding cooperation with the United States by implementing a Single Development Programme for generic medicines, particularly for complex generic medicines would remove redundant studies, decrease inefficiencies and improve patient access [7].

Recommendations:

- Actively engage with countries or regional groupings to promote regulatory convergence efforts for global sustainable access to medicines during trade negotiations in existing bilateral fora and multilateral initiatives (including ICH, IPRP, ICMRA, PICS[8]), to **harmonise regulatory standards, accelerate capacity building and move towards more reliance and convergence in generic and biosimilar medicines approval**. Examples of regulatory convergence include:
  - Exploring new **Mutual Recognition Agreements** (MRAs) for pharmaceutical Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) with partners that have appropriate standards.
  - Taking a global leadership role in the development of strategies to allow the use of foreign comparator products to allow **single global development** for generic and biosimilar medicines.
  - Continuing to foster **international regulatory collaboration** to support strengthening the capacity building, efficiency and effectiveness of regulatory authority bodies globally.
  - Expanding **regulatory reliance** opportunities to facilitate the recognition of medicines approvals granted by WHO Maturity Level 4 authorities or other collaborative instruments (e.g. WHO Prequalification or collaborative procedure) as a bridge to broader access and a way to strengthen regulatory capability and capacity. [9]
  - Promoting **implementation and compliance** with international guidelines (including ICH and WHO). For example, the 2022 WHO Biosimilar Guideline can foster more efficient regulatory systems, enabling earlier access for patients to safe, effective, high-quality and affordable biosimilar medicines.

[7] Association for Accessible Medicines - Medicines for Europe (2024), Joint-statement-AAM-MfE-EU-US-TTC5.pdf

[8] ICH - International Harmonisation Council; IPRP- International Pharmaceutical Regulators Programme, ICMRA- International Coalition of Medicines Regulatory Authorities; PIC/S- Pharmaceutical Inspection Co-operation Scheme

[9] A positive example is the WHO Collaborative Registration Procedure (CRP), a voluntary reliance mechanism that enables National Regulatory Authorities (NRAs) to accelerate the registration of medical products by using assessment reports from WHO Prequalification or other trusted regulatory bodies.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on LinkedIn and X @medicinesforEU.