Your Generics & Biosimilars Industry

July 2024

A new transatlantic partnership for the secure supply of medicines

The European Union and the United States are each other's main trading partners for medicinal and pharmaceutical products, which are the EU's most significant exports to the US and the second most significant US exports to the EU.[1]

Chemical and pharmaceutical products represent 24% of EU exports to Canada and 17% of EU imports from Canada.

On both sides of the Atlantic, generic and biosimilar medicines play a critical role in enhancing patient access and healthcare sustainability, accounting for 70% of medicines prescribed in the EU and 90% of prescriptions filled in the US.[2] Almost 77% of all prescriptions dispensed in Canada in 2023 were for generic medicines.[3]

Most critical medicines are off-patent medicines in the EU, the US and Canada. 9/10 medicines on the EU Critical Medicines List have a generic or biosimilar medicine on the market, for example. While the EU, the US and Canada have been pioneers in the creation of the generic medicines industry (and for the EU, a pioneer in the creation of the biosimilar medicines industry), over time, they have become dependent on a limited number of third countries for the supply of medicines or key components such as active (bio-)pharmaceutical ingredients, key starting materials or intermediates.

Additionally, all three markets are characterised by unsustainable pricing and procurement policies. In most EU Member States, procurement is primarily based on the lowest price criterion, which has resulted in further significant pressure on generic medicines pricing, leading in turn to consolidation and an increased risk to supply security.[4] In the US, shortages are more common in medicines with very low list prices, with 11% (70 of 631) of drugs priced less than $1.00 per extended unit in shortage, compared to 1.3% (3 of 238) of those priced more than $500 per unit.[5] In Canada, since 2007 the average price of generic prescription medicines has fallen by nearly 60 percent, with prices of some of the top-selling generics dropping by an average of 80 percent.[6]

The US has initiated several projects to reduce certain manufacturing dependencies, while the EU has launched the Critical Medicines Alliance to consider the options to strengthen manufacturing in Europe and create strategic partnerships to improve security of supply. Since manufacturing requires scale and volume to be sustainable, it would make sense to assess how the EU, the US and Canada could cooperate to reduce dependency from other regions in terms of supply of medicines. Some of the transatlantic synergies could be:

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[1] Eurostat, USA-EU – international trade in good statistics, February 2024

[2] Association for Accessible Medicines - Report: 2023 U.S. Generic and Biosimilar Medicines Savings Report | Association for Accessible Medicines (accessiblemeds.org)

[3] Canadian Generic Pharmaceutical Association, The Value of Generic Medicines to Canada's Healthcare, Economy and Communities (canadiangenerics.ca)

[4] European Commission, DG SANTE, Future-proofing pharmaceutical legislation – Study on medicine shortages – Final report (revised), December 2021

[5] IQVIA Institute report, Drug Shortages in the U.S. 2023, November 2023

[6] Generics360 – Generic Drugs in Canada, 2018 (pmprb-cepmb.gc.ca), August 2019

- The EU and the US as well as the EU and Canada have a mutual recognition agreement on GMP which is an important regulation that can impact the supply of quality assured medicines. This is a clear advantage for transatlantic cooperation, confirming the importance of regulatory convergence and harmonisation of standards for pharmaceuticals to ensure the highest quality of products and facilitate trade.
- The EU still has a sizeable API industry and both jurisdictions have large chemical industries that could play an important role in reducing critical dependence on third countries.
- The US, the EU and Canada have large scale sterile and biological production which are often critical and may be important for certain risks of health crises (i.e., biological production may be used or repurposed for large scale vaccine production).
- The EU, the US and Canada have multiple treaties and agreements on trade, investment and security that would be conducive to a medicine security partnership. In addition, the US BARDA and EU HERA have a close cooperation since the inception of the EU health security authority.

A Transatlantic medicine security partnership would be aligned with the recent calls from the European Parliament to increase EU-US cooperation to facilitate essential access to medicines[7] and build resilient supply chains,[8] as well as with the European Council call to work together with the US to strengthen strategic resilience[9] and the 2023 EU-Canada Summit joint statement on the need to reaffirm the strategic partnership and advance cooperation to respond to pressing challenges.[10]

The EU-US Trade and Technology Council would be an appropriate forum to discuss a medicine security partnership between the EU and the US given its role in coordinating approaches to key global trade, economic and technology issues, and to deepen transatlantic trade and economic relations based on shared values. The EU-Canada Joint Cooperation Committee established under CETA is already discussing issues related to security of supply and enhanced cooperation in various strategic sectors.[11]

However, a stronger focus on (bio-)pharmaceuticals and active (bio-)pharmaceutical ingredients, considering their strategic value recognised by the EU, the US and Canada and the current geopolitical scenario, is imperative in order to safeguard patient access on both sides of the Atlantic.

In particular, we believe it is essential to collaborate on:

- **Security of medicines supply**

The EU, the US and Canada are exploring ways to diversify their supply chains to reduce dependence on limited number of supplying countries for APIs and finished dose production. The EU and the US have collected data on dependencies and strategic autonomy.

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[7] European Parliament resolution of 6 October 2021 on the future of EU-US relations

[8] European Parliament recommendation of 13 December 2023 to the Council, the Commission and the Vice-President of the Commission/High Representative of the Union for Foreign Affairs and Security Policy concerning EU-US relations

[9] European Council conclusions on European Union – United States relations, 7 December 2020

[10] EU-Canada Summit 2023 - Joint Statement, 24 November 2023

[11] EU-Canada: 4th meeting of the Joint Cooperation Committee under the Strategic Partnership Agreement, 9 March 2023

A joint initiative focusing on the transatlantic market, rather than the EU or the US or Canada market alone, would leverage the strength of each market to enhance the health security of the three regions.

The initiative should encourage an exchange of analyses, information and ongoing thinking, as well as foster collaboration regarding needed investment in R&D, capacity expansion, manufacturing and sustainable market policies.

- **Solidarity-based responses to crises**

The Covid-19 pandemic confirmed that export restrictions during a health crisis exacerbate panic in (bio-) pharmaceutical production and markets and undermine the solidarity needed to overcome a global crisis.

The EU, the US and Canada should collaborate to avoid that export restrictions impact the bilateral supply chain and promote cooperation in multilateral fora to prevent protectionist responses to future healthcare crises.

- **Bilateral and multilateral regulatory cooperation**

Introducing a Single Development Programme for complex generic medicines would eliminate unnecessary and unethical duplication of studies, cut inefficiencies in development programmes and better address patient needs.

International collaboration to foster regulatory harmonisation and reliance would also be key to expedite patient access to generic and biosimilar medicines globally.

By focusing on these areas, the EU, the US and Canada can strengthen their partnership to ensure better patient access to medicines, enhance healthcare outcomes, bolster security and foster increased investments.

Association for Accessible Medicines

AAM is driven by the belief that access to safe, quality, effective medicine has a tremendous impact on a person's life and the world around them. Generic and biosimilar medicines improve people's lives, improving society and the economy in turn. AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals are 90 percent of prescriptions dispensed in the U.S. but only 17.5 percent of total drug spending.

Canadian Generic Pharmaceutical Association

CGPA represents Canada's generic pharmaceutical industry. Its Biosimilars Canada division represents the biosimilar medicines industry. The industries play an important role in controlling health-care costs in Canada. Generic drugs are dispensed to fill 76.9 percent of all prescriptions but account for account for only 22.3 percent of the $43.8-billion Canadians spend annually on prescription medicines. Canada is also home to a globally significant cluster of generic manufacturing facilities, which is a strategic asset for Canada that directly employs more than 11,000 in highly-skilled positions. The use of biosimilar medicines in Canada is expanding rapidly, contributing to the sustainability of drug benefit plans and supporting investments in expanded prescription drug coverage. Biosimilars are now used to fill 10.8 percent of retail biologic prescriptions in Canada, and are also used extensively in Canada's publicly-funded provincial cancer care systems. For more information, please visit us at www.canadiangenerics.ca and www.biosimilarscanada.ca and follow us on LinkedIn at @canadian-generic-pharmaceutical-association and @biosimilars-canada.

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 for Europe, 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. 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 at @medicinesforEU.